Boulder iQ
Innovation to Quality

Boulder Sterilization

RA/QA | Engineering | Manufacturing | Sterilization

About Us:

Boulder iQ is a full-service medical device engineering development & manufact-uring firm with regulatory affairs, clean room assembly and on-site EO sterilization. Boulder iQ focuses on efficient processes for best possible "time to market."

From the Desk of Founder: Jim Kasic

Tips to make your company more investable: I love medical device statup companies! Acquiring adequate investment capital during the process is critical. In order to reach that wonderful day when you are revenue positive and self-sustaining, you have to make it through the "Valley of death," that famous period between initial "seed" or "family &

friends" funding and adequate capitalization to reach positive cash flow. Here are a few tips from my own experience in fundraising...

Read More Below

In this Issue:

We take a look at a variety of topics from *Sterilization Contracting* to the *EU's New Regulatory Basis* and *Early-Stage Medical Device Valuation Strategies*

How to select a Sterilization Contractor

7 Factors to Consider While Selecting a Medical Device Sterilization Contractor and How They Can Benefit Your Medical Device Company

Read More

The New EU: IVDR and Economic Operators

How the IVDR Replacing the IVDD Will Affect AR's, Importers, and Distributors Along with the Adoption of the New Economic Operator (EO)

Read More

Valuation Strategies for Early Stage Med Device Companies

A Step-By-Step Article Covering How to Build Value in Your Company to Attract Funding and Turn Your Entrepreneurial Dreams into Reality

Read More

Think Smart: Eliminate the Gate in 'Phase-Gate' Approach

As Featured in Med Device Online: How Boulder iQ's "Think Smart" approach to product development can save time – and money – in getting life sciences products to market.

Read More

From the Desk of Founder: Jim Kasic (cont.)

... Please note that in this issue we also feature part one of a two-part article by Colorado serial medical device entrepreneur Larry Blankenship regarding how to increase your company's valuation. These tips and that article should give you valuable insight.
Below is the list of my seven tips, followed by expanded comments on each. Our startup company's product:

1. Either does something new, does the same thing for a lower price, or does more for the same price
2. Has a clear FDA pathway
3. Has reimbursement
4. Has a high margin ~ 85%
5. Has a high price
6. Has IP
7. Has a defined market

Before I discuss these tips, however, let's talk about risk reduction in general. An investor wants to put money into ventures that have a high likelihood of success, with as many of the risk factors as possible already mitigated. Many venture capital (VC) firms only invest in companies that are beyond the startup stage for this very reason. Startups are inherently risky as there's so much to do to reach steady and growing revenues. For those investors who are interested in startups, you can increase your attractiveness by addressing these factors in your company's product:

1. **Either does something new, does the same thing for a lower price, or does more for the same price**
    - In Clayton Christian's famous book "The Innovator's Dilemma: When New Technologies Cause Great Firms to Fail," he gives examples of established products that are crushed by new entries. One example is the dot-matrix printer. When was the last time you saw one of those? Yet, in the 1980's they dominated the printer market. Reams and reams of paper with perforated hole-punched

tracks on each side were sold in large volume. Laser printers were still early in their development, and expensive. Enter the inkjet printer. As small or smaller than the dot-matrix, full color, less expensive and much quieter (thank goodness!).

- If your product does something that the market must have and does it significantly cheaper, better and/or does more, you can have an attractive investment opportunity.

2. **Has a clear FDA pathway**
    - Regulatory hurdles can be major risk factors to start up medical companies. Don't assume that you have a simple, easy way to obtain regulatory clearance if you haven't confirmed it.

    - There are many "horror" stories about companies who thought they had a clear pathway and later found otherwise. Among these are drug delivery devices that think they are a simple pumping or transfer mechanism and then find they are classified as a "combination product" by the FDA and have to show that their drug container provides long-term stability for its contents. Now instead of a 510(k), they're facing lengthy, expensive drug storage testing to confirm that there is no interference between their device and the drugs intended to be delivered. Ouch! Other such stories include devices that try to combine predicates in a 510(k) application which independently have separate indications of use which the new product wants to incorporate. Instead of a 510(k), the company might be looking at a de novo application process which is lengthier and more involved. And don't assume you will not be required to present a CER, or Clinical Evaluation Report. Some 510(k) products are cleared without clinical data requirements, but certainly not all. To assume incorrectly that no clinical data will be required can lead to a grossly underestimated timeline and budget.

    - In some cases, when predicate devices have the same indication as your device and have been cleared in recent years without clinical data, you may have a strong case that your FDA pathway is predictable and straightforward. If there is any question, however, at least get an opinion from a regulatory affairs professional, or ask the FDA to classify your device by submitting a 513(g) application.

    - By paying attention to this area and having a strong, convincing argument that your regulatory pathway is clear and has been properly timed and budgeted, you will reduce one of the major investment risks associated with healthcare products.

3. **Has reimbursement**
    - A colleague once told me that all medical devices must satisfy the "3 P's." That is, they must be attractive and have advantages to the Patient, the Physician, and the Payer. We all want to create devices

that have clinical benefits, but they must also have economic benefits!

- A purchasing agent has to justify that your product is necessary and affordable. Even if a physician requests it, it is the purchasing department's responsibility to make sure that the physician's need is satisfied adequately at the lowest cost. One way to help assure acceptability is to show how your product can be paid-for within current reimbursement structures. Those include products used to treat payments under DRG (Diagnosis-Related Group) reimbursement and through CPT (Current Procedural Terminology) codes.

- A DRG reimbursement is associated with a patient's diagnosis. Typically, a diagnosis is associated with a fixed dollar-amount of reimbursement. The healthcare provider is expected to treat the diagnosis for this fixed amount. If your product can help them do that for less money, then you may have an advantage in their system.

- CPT code reimbursements are associated with the physician's specific skills and use of equipment and tools to perform a particular procedure. For example, special training and qualification is required to perform cardiac catheterization procedures. The CPT code provides additional reimbursement for the special skills and equipment necessary to perform this treatment. Obtaining new CPT codes is a lengthy process typically requiring two or more years of experience and a number of peer-reviewed publications attesting to your product's advantages. You may, however, fit within existing CPT codes, which will give you an economic advantage.

- The bottom line on this category is that an investor wants to make sure that the market will be willing to accept and pay for your product, thus lowering market risks.

4. **Has a high margin ~ 85%**
    - Medical devices are valued based upon the importance they have to a particular procedure, and not so much on their manufacturing costs. If you have a unique advantage and provide excellent value to all of the 3 P's, the Patient, the Physician, and the Payer, you may be able to achieve high margins between the ASP (Average Sales Price) for your product and its COGS (Cost Of Goods Sold). This gross margin can be in the mid-80% range for excellent returns. Margins above 70% are also attractive. The key to achieving such margins is to provide a unique value.

    - Uniqueness is temporary, however, as others will try to copy your product unless it is unlawful for them to do so, such as you have a patent or other Intellectual Property (IP – see below). The US and international community grant an inventor a monopoly to profit from their invention for 20 years from the initial patent filing date,

after which the patent information becomes usable by all. After that, the aspects of your product covered by that patent can be freely copied by others. Smart product developers maintain their high margins over the longer-term by finding ways to maintain their uniqueness through IP and other means.

- Investors are looking for a solid story of why you can expect high margins and how you will maintain those over a reasonable period of time.

5. **Has a high price**
   - In the first half of the twentieth century there was such a thing as "penny candy." For a child to purchase a piece of candy for a penny was fun and inexpensive. But no matter how high the gross margin the manufacturer obtains on that piece of candy, they're never going to make a huge amount of money. The selling price is just too low.

   - Most medical products would like to demand a per-use price in the hundreds or thousands of dollars. While there are exceptions, many factors in the medical device field make this possible and also necessary. Look at the number of procedures performed each year that would use your product. It's probably not in the millions per year as very few medical procedures are performed in such volume, though they do exist. If it's in the hundreds of thousands, perhaps even in the tens of thousands of cases per year, you have a good opportunity to make a product that can be produced in volume, at high margins and likely demand a price that will provide good returns to you and your investors.

   - There is also a significant cost in selling a product, that is, convincing the physician and payor to purchase it. Just image that it costs $5000 on average for sales and marketing to convert a customer and your product sells for $5000 with an 80% gross margin. It's likely that your net profit from this sale will be about 20%. Therefore, you would need to sell 5 devices to cover your acquisition costs and start making positive cash flow from this customer. However, if your average sales price is $500, then you would need to sell 50 devices to cover your customer acquisition costs.

6. **Has IP**
   - As discussed in the High Margins section, maintaining uniqueness over a long period is a key to avoiding becoming a generic commodity product. The most common and recognized way to obtain and retain uniqueness if by obtaining one or more patents on your product. There are other ways to retain uniqueness, such as by maintaining trade secrets on how the product is produced, but those are harder to confirm, defend and value. Patents can be analyzed and assessed for their monetary value in a particular market area, so are preferred by investors.

- Showing solid IP protection, at least through reviewable patent applications, will be important to professional investors. You'll also want to present an IP strategy of ongoing innovation and invention to enable an overlapping string of patents.

7. **Has a defined market**
    - Who's going to buy your product, and do they already know that they will? If so, explain why. This is important. There's such a thing as a "missionary" sales project. That's where your customer has to be convinced to "believe" in a new product concept, especially one which requires a change in their current procedures. This is very hard to achieve and is also a very lengthy process. The ideal market is a specific medical treatment area or diagnostic process where your product clearly fits into and enhances their current procedures.

    - Recently, Boulder iQ announced that the startup company CardioScout Innovations, Inc. has been accepted into the Boulder Medical Device Accelerator program. CardioScout's product concept is a device to access the outside surface of the heart, the epicardium. Many advanced cardiac centers are already performing epicardial procedures, but with tools that were not designed for this use. They're using them "off label," meaning in a different manner than their FDA clearance prescribes. Since the epicardium is a significantly different bodily area accessed in a very different manner than in other procedures, using tools off-label is awkward and time consuming. The CardioScout device will make epicardial access much faster and easier, and all of the advanced cardiac centers already practicing epicardial procedures with off-label tools will purchase the CardioScout device as soon as it's available.

    - A market that is eager for a device to answer an unmet need, especially if that need is obvious, is the best kind of "defined market." It has a defined sales call-point, in this case cardiac specialists, it's used in the OR or Catherization Laboratory, of which there are a defined number in the USA, and we can easily identify where they are, and it will be used in procedures that are already performed. Further, the physicians already know they need a new way to do this. If you can find a similar set of market attributes for your product, you'll be on your way to attracting investors!

In summary, make your startup company attractive to investors by thinking about the potential benefits of investing from the investor's perspectives – what's important to them, and why. Then make sure you have all the key points covered when you interact with them.

This is a great business to be in, with opportunities to help people and our economy. Congratulations to you entrepreneurs who are giving it a try! At Boulder iQ, we're dedicated to helping you. Please contact us to discuss how we can help you.

Happy and successful fundraising!
Jim

7 Factors to Consider in Selecting a Medical Device Sterilization Contractor

By Peggy Fasano, M.B.A., COO, Boulder iQ, Boulder, CO

For medical devices, sterility is one of the most important steps in development and production. In today's world, sterilization, and the decision on selecting a sterilization contractor are more critical than ever.

How fast companies can get their products to market can mean success or failure of the product, the company and, in many cases, the end user. Most companies have no time to waste, yet many sterilization companies are at maximum capacity dealing with suppliers and prioritizing the highest volume most lucrative customers leaving limited supply for other companies and customers. Current market dynamics require careful attention to identifying, evaluating, and choosing a quality, reliable contract sterilization vendor. To assist in that process, Boulder Sterilization Services (BSS) offers the following seven factors to consider:

1. **Turnaround Time** - The time to sterilize and validate products and get them to market quickly is of utmost concern. However, you must be able to balance this with reliability, process integrity, cost and the availability of other services to integrate that may speed market introduction.

2. **Scalability** – Small device companies often focus, understandably, on immediate needs, but it's important to also look at the ability of the sterilization contractor to scale for future business. That scalability may come in the form of sterilization capacity as well as abilities of the company to handle other services that will accelerate time to market.

3. **Cost** – As with many products and services, it's usually neither the least expensive nor most expensive vendor that is the best. Look for a sterilization vendor that meets your needs, is reliable, and whose staff is professional, sharp and easy to work with.

4. **Process Controls** – How the vendor handles segregation of processed and unprocessed product is critical for quality control. Make sure you understand how the sterilization contractor confirms that its process provides clear segregation.

5. **Green Operations** – Evaluate the process the sterilization contractor uses. Over 50% of medical devices are sterilized using Ethylene Oxide (EO) to protect the sensitive materials in the devices. With the proper infrastructure, EO can be a great, safe, and effective low-temperature sterilization method. Search out companies that use an abator (catalytic converter) system to mitigate release of specific gases into the atmosphere.

6. **Customer Service** – Finding a vendor that will communicate and work with you is very important. As sterilization is a critical step in the development and manufacturing processes, find a vendor that will serve your needs, maintain compliance with your regulatory bodies including allowing audits, answer questions promptly, and ensure their services are a good fit.

7. **Additional Services** – For many medical device companies, working with a vendor that it is a "one-stop shop" makes all the difference in getting products to market. "Often, medical device companies will work with separate design, manufacturing and compliance consultants," explains Jim Kasic, Founder and Chairman of Boulder BioMed. "They end up losing valuable time, energy and resources coordinating between them." Instead, he says, the right contract firm may be able to offer all services under a single roof, drastically reducing the amount of effort and time a client must otherwise expend to coordinate between the different functions.

Because the choice of a sterilization contractor impacts cost, efficiency, convenience, ultimate time to market and your ongoing product flow, it is a critically important step for medical device manufacturers. Companies that take a little time up front to consider these factors will reap the rewards for years to come

June 2021

The New EU: IVDR and Economic Indicators

The New EU: IVDR (In Vitro Diagnostic Medical Devices Regulation) and Economic Operators

By Mike Andrews, Ph.D., Vice Pres. Regulatory and Quality, Boulder iQ, Boulder, CO

Introduction - The EU In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) will replace the EU In Vitro Diagnostic Medical Devices Directive 98/79 (IVDD). Compliance with the IVDR is required no later than May 26, 2022. The IVDR introduces some new terms, some new players, and assigns obligations beyond those found in the IVDD to some existing players. The main new term in the IVDR is Economic Operator (EO). This term refers to EU Authorized Representatives (AR's), importers, distributors, and manufacturers, who are all required to register as EO's in the EUDAMED database. We will explore in more detail the requirements for AR's, importers, and distributors.

Authorized Representative The IVDR adds a number of responsibilities for the AR. The most significant new responsibilities are as follows:

- The AR must have a written mandate for designation (previously it was "explicitly designated")
- The AR must immediately terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.
- An authorized representative who terminates must immediately inform the competent authority of the Member State in which it is established and the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons for the termination.

- The AR's are now jointly liable for defective devices if the manufacturer is not carrying out its obligations under the IVDR.
- The AR must maintain records for 10 years after the last device has been distributed. It was previously 5 years after the last device had been manufactured.
- The AR may request a Certificate of Free Sale on behalf of the manufacturer.

This means that the contract between the manufacturer and the AR will have to be carefully drafted so that it includes all of the AR's responsibilities under the IVDR. And the AR now has a role in maintaining compliance with the IVDR.

Importer Importers were not even mentioned in the IVDD. Thus, their responsibilities are all new. The most significant new responsibilities are as follows:

- Before making a device available on the market, the importer must verify that:
    - the device has been CE marked and that the Declaration of Conformity for the device has been drawn up;
    - a manufacturer is identified and that an authorized representative has been designated by the manufacturer;
    - the device is labelled in accordance with this Regulation and accompanied by the required instructions for use; and
    - where applicable, a UDI has been assigned by the manufacturer
    - If an importer believes that a device is not in conformity with the requirements of this Regulation, the device is not to be placed on the market until it has been brought into conformity The manufacturer and the manufacturer's authorized representative are to be informed. If the importer believes that the device presents a serious risk or is a falsified device, the Competent Authority of the Member State in which the importer is established is to be informed, and if applicable, the notified body that issued a certificate for the device in question.

If the device has been placed on the market, the importer would have the responsibilities described above.

- Importers are to keep a copy of the Declaration of Conformity and, if applicable, a copy of the relevant certificate

As in the case of the AR, the contract between the manufacturer and the importer will have to be carefully drafted so that it includes all of the importer's responsibilities. The importer, like the AR, now has a role in

maintaining compliance.

Distributor Like the Importer, the Distributor was not even mentioned in the IVDD. Thus, all of the responsibilities under the IVDR are new. The most significant new responsibilities are as follows:

- Before making a device available on the market, verify that:
  - the device has been CE marked and the Declaration of Conformity of the device has been drawn up;
  - the device is accompanied by the information to be supplied by the manufacturer in accordance with the IVDR; and
  - where applicable, a UDI has been assigned by the manufacturer.
- If a distributor believes that a device is not in conformity with the requirements of the IVDR, the device is not to be made available on the market until it has been brought into conformity. The distributor must inform the manufacturer and, where applicable, the Authorized Representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established and, if applicable, the notified body that issued a certificate for the device in question.
- If the distributor has already placed the device on the market, the distributor would have the responsibilities described above.

As in the case of the AR and the importer, the contract between the manufacturer and the distributor will have to be carefully drafted so that it addresses all the distributor's responsibilities.

Person Responsible for Regulatory Compliance Though not an Economic Operator, the requirement for a person Responsible for Regulatory Compliance impacts the Manufacturer and the AR. Both must now identify a Person Responsible for Regulatory Compliance within their organizations. This responsibility may be shared by more than one individual. A micro or small enterprise does not have to have this person on staff but may contract for the position. The name, work address, and contact details of the person or persons responsible for regulatory compliance must be part of the information provided when the manufacturer or authorized representative register.
This Person must have certain expertise in the field of in vitro diagnostic medical devices. That expertise must be demonstrated by either:

1. a diploma, certificate, or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognized as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in

quality management systems relating to in vitro diagnostic medical devices; or

2. four years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices.

Responsibilities of the Person Responsible for Regulatory Compliance within the manufacturer's organization include:

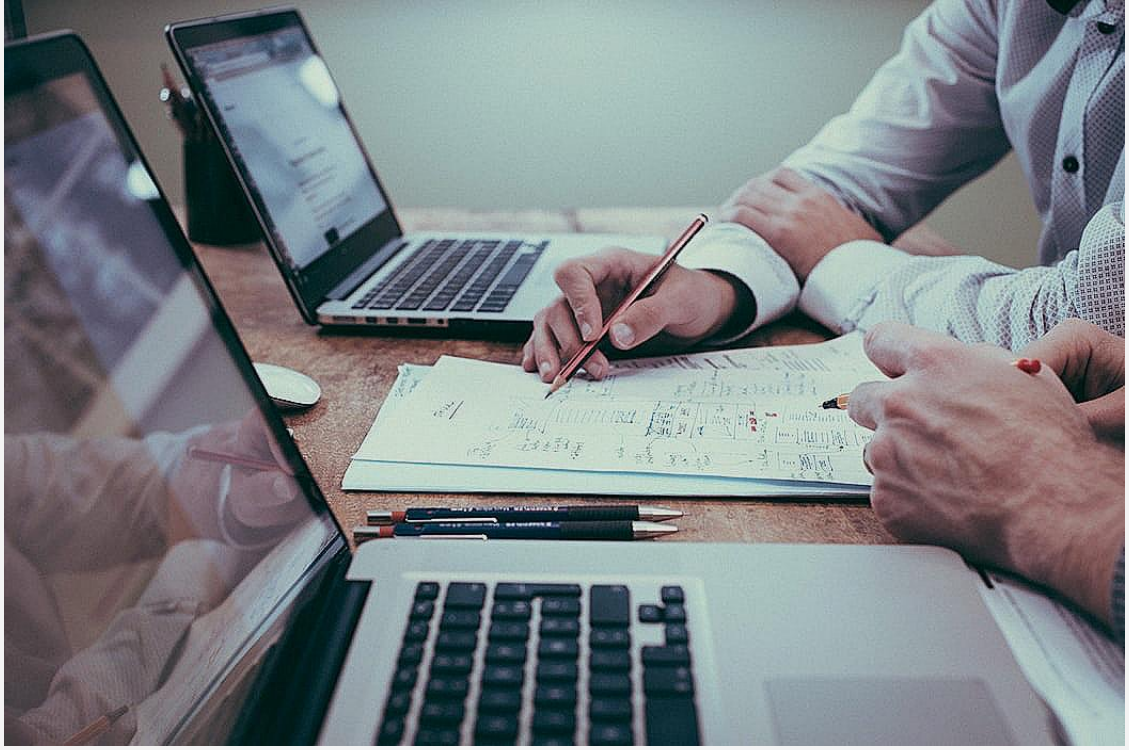
- checking the conformity of the devices, in accordance with the quality management system, before a device is released;
- assuring that the Technical Documentation and the Declaration of Conformity are drawn up and kept up to date;
- assuring that the post-market surveillance obligations in the IVDR are complied with;
- assuring that the vigilance reporting obligations referred to in the IVDR are fulfilled

Traceability Under the IVDR, EOs have responsibilities for traceability. Distributors and importers must cooperate with manufacturers or ARs with respect to the traceability of devices. An EO must be able to identify any EO they have directly supplied with a device, any EO that has directly supplied them with a device, and any health institution or healthcare professional they have directly supplied with a device. These distribution records must be maintained for 10 years after the last device has been placed on the market.

Conclusion Several organizations and individuals are going to need to look very carefully at the details of the IVDR and prepare for the May 26, 2022, deadline. Importers and distributors are now in the spotlight with a series of brand-new responsibilities. The Person Responsible for Regulatory Compliance has his or her own set of responsibilities and all the Economic Operators have requirements with respect to traceability. As companies prepare for the new IVDR, they will need to think how the new requirements for Economic Operators affect their business and products.

June 2021

Valuation Strategies for Early Stage Med Device Companies



Valuation Strategies for Early Stage Medical Device Companies (Part 1)

By Larry Blankenship, Principal, Blankenship Research

Hopes and Dreams

To be an entrepreneur in the medical device field, you must have a compelling vision, a goal, a dream, a passion. But a dream without a plan is just a wish. You are probably working hard at building your company, perfecting your product idea and making real progress. But a company without funding is just a hobby, and hope is not a strategy.

I've had many dreams that were merely wishes and companies that turned out to be hobbies. This article is focused on key steps to bring your dreams into reality and build value in your company to attract funding.

Who Cares?

These two words are truly the key to success. You care, but who else? The "who" in the question is of paramount importance. No investor will write you a check unless they're compelled to do so. Somebody has to care about what your doing – very much. And that somebody needs to truly *be* somebody. Investors are people, driven by their own dreams and passions. They're also driven by trends and data and they look to key leaders to get a sense of where things might be headed. Let's say you have an idea for a medical device to address what you perceive as a clinical need. Oh yeah? Who are you? You might be an MD, which will give you some credence to be sure, but you're also the inventor, so you have an inherent bias. Who else cares? The investors will look beyond you to see who else is passionate about your idea – and where they come from.

I've found that if I'm pursuing a concept that can truly make a difference in medical procedures and outcomes, I have no problem getting an audience

with the best, most renowned physicians in the field. Remember, the top physicians got there by being leaders. They retain their position and their prominence by staying ahead of the field. Investors may not know the names of the physicians, but they'll know the best hospitals and clinics – household names. If I say my chief medical advisor is a doctor from Podunk State, that's not nearly as impressive as the chief of the department of medicine at Johns Hopkins or The Mayo Clinic or Stanford. That's who cares! Now I've got the investor's attention.

The Steps

Over the years I have developed the following "7 Steps" to increasing a company's value. I have done this through direct involvement with four medical device startup companies and advisory positions, and observation of dozens of others. While they are executed approximately in order, there is significant overlap, and if changing the order of some of the steps has advantage for
your venture, then do it! It is my hope that the suggestions that follow will be of real value to you and your colleagues as you pursue your entrepreneurial path. *You* are the future of medical devices. You are on a noble journey!

Step 1: Choose the Right Project

There are patterns and trends in healthcare investing. In the 1980s, coronary artery bypass graft (CABG) procedures were expanding from research institutions to community hospitals. Tools and techniques to improve CABG procedures were being developed by many startup companies, including mine, and significant investment money was available. In the 1990s, catheter approaches with angioplasty and stents began taking over the market, followed by drug-eluting stents to reliably open clogged coronary arteries. Today, advanced techniques for congestive heart failure, transcatheter mitral and tricuspid valve replacement, and techniques for control of cardiac arrhythmias are being funded. As a result of these new technologies, CABG procedure volume has dropped dramatically and is expected to continue its decline. Let's say, however, I have a way to make the CABG procedure better than it is today. That could be an important contribution for the people who still face enduring that procedure, but I would be shown the door of the VC office before I ever got a chance to present my idea. It's old hat! The future lies in new procedures, methods and technologies.
The moral of the story: Choose an idea that's *fundable!*
It goes back to the "Who cares?" question. Investors care about helping patients, yes, and they also care about being trend-setters and investing in expanding markets. So even if you have a good idea, trying to get it funded for a shrinking market will be a very hard sell.
Do your market research! It's not hard to find statistics regarding how many procedures are done annually or where the key problem areas lie. I'm currently working on a product to help deal with Ventricular Tachycardia (VT). Over 300,000 deaths in the USA annually are related to VT. That's *huge!*

Today, the primary therapeutic approach is through RF ablation applied through a catheter inserted through the groin and threaded into the heart. But that procedure's only around 70% effective depending on the specific aetiology, has a relatively high recurrence rate, and almost 20% of the patients receiving that therapy return to the hospital within the first 30 days.
Conclusion: Something new is needed! So, let's work on that problem!
In looking into the possibilities of a new device to help with VT, I and my colleagues talked to some of the leading electrophysiologists in the country – they were universally enthusiastic. We talked to sales companies who serve that market and were told "That's a gamechanger! If I had that product today, I could sell it today!"
So, if you're going to put the terrific amount of energy, passion and likely years of your working life into a new project – choose one that receives *that* kind of enthusiastic support.

Step 2: Protect Your Ideas

When there is significant money to be made, there will be plenty of people trying to take advantage of that opportunity. You *will* have competition. Competition is not a bad thing; it
confirms and validates your market opportunity. As long as you're going into a relatively uncrowded application area (a so called "blue ocean," i.e., not yet turned red by all the sharks feeding), a limited number of competitors, each with novel technologies, have the ability to share the market and all prosper. Eventually one or two of the technologies will become dominant and the others will fade away. An example is what happened as CABG was being replaced by other technologies to address coronary artery blockage. Balloon angioplasty with drug eluting stents has captured that market, but other techniques, such as atherectomy, were competing for a while. Atherectomy, which drills out or scrapes away the material clogging the arteries proved not to be as effective, easy or safe in many situations, and is only used today in special circumstances, not mainstream diagnoses.
All of these technologies were/are protected by patents. If you want to design a new coronary artery stent today, you'll find the patent landscape a minefield to traverse. Finding a way to be novel after so many innovators and companies have spent so much time and money investing in that field is likely to be very difficult. Yet, there are a few new ideas still emerging.
When you get a good idea, make sure you don't share it with anyone who hasn't signed a Non-Disclosure Agreement (NDA). And when the idea is developed well enough for you to sketch and describe the approach you have in mind as well as other potential approaches, file a provisional patent. That buys you one year. Only one year before you have to file a PCT patent application (Patent Cooperation Treaty) and/or one or more national applications (i.e., applications in specific countries).
In your provisional, PCT, and national patent applications, it's important to describe all of the ways and variations that you may use to implement your idea. It's also important for you to describe other ways to address the problem, even if you do not intend to implement them yourself. Go crazy! List every way you can possibly think of! This is known as a "blocking" strategy. If

you have revealed all of these different ideas in your patent, that can block others from patenting those competitive ideas themselves.
While patents are not the only way to protect your ideas, they are the most calculable. One patent, or a portfolio of patents can be analyzed relative to potential competition, strength of claims, and the ability that your intellectual property (IP) gives you for "freedom to operate" in your chosen field. The value of patents can be expressed in quantitative, monetary terms. This becomes part of an evaluation of your overall company value and plays into the potential terms you might be offered by venture capitalists or other investors. Trade secrets and other ways of protecting your ideas are less tangible and therefore hard to value (i.e., worth less value in the negotiations).

Step 3: Address the 4 Key Risk Areas

1. Market Risk: If you build it, who will buy it? For how much? Are you sure? Why? What's the competitive landscape? Can you protect your idea?
2. Technology Risk: Will it work? What makes you think so? Who else agrees?
3. Management Risk: Can you and your team execute the plan successfully? You must have a plan, at least in outline/bullet form, with cost and potential revenue projections that can be challenged (they will be). What makes you think your team can succeed? Have they done it before? What outside advisory and other help have you secured to help assure your success?
4. Regulatory Risk: What's the regulatory classification for your product? The requirements for approval or clearance? How sure are you? What's your regulatory strategy? Have you built this into your business plan in a conservative way? Who are your regulatory advisors? Have you talked to the FDA and/or an EU Notified Body? Many companies have been significantly delayed or put out of business by not understanding and managing this risk.

Your business plan and your presentation to potential investors must include all of these factors. The investors know the risks. They want to see how much *you* understand the risks and how you intend to mitigate them. Once you're on the market and making money, investing in your company is much less risky, since you have an already proven business model. But if you're a startup, the risks of ever getting to commercialization must all be considered in detail. There are a number of professional investment firms who are comfortable with pre-revenue and early-stage companies. They are very aware of the additional risks and are looking for how you as a leader and your management team are planning on dealing with those risks. Go in with your

eyes open! Know that your investors are experts at understanding these risks, and they're going to want to see that you are, too.

To be Continued in our Third Quarter Newsletter. The second part will focus on the finding comparables, making progress, getting the word out, building key relationships and managing to persevere. Stay Tuned!

Contact me if I can be of help to you and best wishes for astounding success!

larry@blankenshipresearch.com.

April 2021

Featured in Med-Device Online: Think Smart: Eliminate the 'Gate' in 'Phase-Gate' Approach

How to Eliminate the Gate in Medtech Product Development's Phase-Gate Approach

By Peggy Fasano, M.B.A., COO & Jim Kasic M.B.A., CEO & Chairman, Boulder iQ, Boulder, CO

As part of the FDA's regulations, every medical device developer must establish a quality management system (QMS). In most cases, developers also must establish and use design controls, creating specific documentation and reviewing requirements throughout the process. Those include a design history file (DHF), verification and validation testing, and a device master record (DMR) on the release of the design to manufacturing. Most device companies include a phased product development process in their QMS, outlining specific requirements for each phase. QMS policies require, and strictly enforce, documented design and phase reviews before completing the DHF for that phase of the process. In many cases, these reviews serve as gatekeepers, allowing significant work on the following phase to begin only when the requirements of the previous phase have been met. The result is the

well-known phase-gate approach to medical device development.

The resulting product development process often becomes cumbersome and slow – the exact opposite of what's needed for products whose function is often essential to critical treatment or prevention of disease or chronic conditions. The good news is that there are ways to make dramatic improvements to the efficiency of the product development process while maintaining project phase controls. Speeding time to market within a controlled process is possible but requires thinking differently – thinking smarter – about the order of some steps in the process, focusing on the end result instead of each phase. This "think smart" approach does not skip any required steps. It simply eliminates the "gate" from traditional phase-gate thinking. The result: substantial time savings. In our experience, implementing the "think smart" approach with several hundred companies over 25 years, we have seen time savings of 10 to 60%, depending on the project. That translates to significant cost savings every step of the way.

Draft The Instructions For Use (IFU) In Phase 1

In most systems, writing the Instructions for Use (IFU) document for a device takes place toward the end of the development process when all relevant details are available. Instead, there's a real advantage in drafting the IFU within the first phase of the development as part of the formative usability study (per ISO 62366).

To confirm that the development approach is sound, the formative usability study typically requires document sketches and presentation of concepts to potential users. Drafting the IFU up front saves serious time later on, as it helps the development team better understand the end use of the product. They then can conduct a simple in-service training session with users following the drafting of the IFU.

This approach has a double benefit. Users walk through how they will implement the device, and developers gain perspective and details about how their device will achieve key end goals – all *before* expending substantial time in development. And the resulting impact on the accuracy of the product requirements and specifications can be dramatic, ultimately reducing the number and depth of iterations during the design and testing processes.

Developers can then use information from the IFU – appropriately modified – with the resulting product requirements document and specifications to outline test protocols for engineering performance confirmation and verification and validation. Knowing how the design will be tested very early in the process helps streamline the design activities.

Prep The Table Of Contents First Versus Last

Following the "think smart" approach, it's also possible to develop the table of contents for the DHF and 510(k) at the beginning of the development process. To do so, a company would create a file folder (electronic and/or physical) for each item in the table of contents and begin adding draft documents to them as early as possible.

As later phases near completion, developers will need far less time and effort to complete the DHF and portions of the 510(k) submission, since most of the work will already be done.

Draft Verification And Validation Plans Directly After The Product Requirements

Development of verification and validation plans is often listed as a step in a later phase of the development process. However, the reality is that they can be drafted as soon as the product requirements have been drafted, in Phase 1. The same holds true for other procedures and documents.

By understanding exactly which tests the product will need to undergo at the beginning of the development phase, the engineering team can design the product through the lens of the testing requirements, thereby assuring the product will pass the tests. In the process, they also might encounter a cost-prohibitive test, allowing them to change or shift a specific feature.

The plans, procedures, and documents will almost inevitably change through development and will require refinement for additional information and detail. But doing as much as possible, as soon as possible, provides a foundation that results in major time savings over the life of the development process.

Overcoming Implementation Challenges

Change can be hard for everyone, especially in a professional context where the same methodology – such as the FDA's phase-gate approach – has been used for a significant period. Methods to shift an organization's mindset do exist, however.

Putting the cart before the horse: A common challenge encountered in starting the IFU draft in Phase 1 is that product details are not available, since the product has not yet been designed. That's the point: to be clear on the type of product to design so that it meets the needs of the market. To address the challenge, it's important to talk with the product development team, including those from quality, engineering, and regulatory, at the beginning of the project. By explaining the entire process and including them in writing the IFU, they will better see the overall benefits and become invested in the modified process. They will gain a better understanding of the product, have more "skin in the game," and know their overall role in the process.

"I'll just have to redo it later": A common refrain when implementing the "think smart" approach, the reality is that once the IFU, requirements, and specifications are in place, the developer can draft most of the documents that will be needed later by simply leaving blanks to fill in for the details. To complete each phase, review meetings should confirm the review and appropriate approval of all documents required for that phase. That does not mean that all documents must be prepared, in entirety, just before the review meetings in a massive time-consuming effort. Rather, by "thinking smart," it's possible to draft a large number of documents for future phases, ready for the addition of final details. As an added benefit to preparing documents early on, developers must carefully think about what each will require, thereby avoiding last-minute oversights or rushes to obtain information.

Personnel management: Another challenge can be managing schedules so that the right person is available to do needed work up front. While almost every project will have someone responsible for regulatory work at the beginning of a project, some shifting of schedules may be required. The key is to look at the overall time savings and the resulting decrease in number of days, weeks, and months to get a product to the market.

Templates And Project Management Tools

Each project and each product has its own unique characteristics. After all, product requirements and specifications for an IV pump and tubing set will be radically different from those of an electrosurgical generator and disposable surgical pencils. Templates, then, may be limited but still have value in establishing and completing the major required items.

Project management tools – including Microsoft Project, Playbook, Smartsheet, and Agile – do an excellent job of tracking activities. But they only help implement a specific way of proceeding along the development path. To use tools like these within the "think smart" approach, a design company would simply restructure the tasks and sprints to include early implementation of the IFU, test procedures, DHF and 510(k) submission document structures, and other tasks.

Conclusion

Efficient design depends on a deep understanding of user needs and testing requirements. Developing this understanding from the beginning, and documenting the understanding in appropriate required documents at the time, results in time and cost savings and the ability to introduce innovative products in advance of the competition.

In every field, significant advantages happen by challenging traditional thinking. Medical device development is no different. Thinking smart means thinking in ways specifically targeted to reducing time to market while

maintaining quality and compliance.

About The Authors:

Jim Kasic is the founder and chairman of Boulder iQ. With more than 30 years of experience in the Class I, II, and III medical device industry, he holds more than 40 U.S. and international patients. His career includes experience with companies ranging from large multinational corporations to start-ups with a national and international scope. Kasic has served as president and CEO of Sophono, Inc., a multinational manufacturer and distributor of implantable hearing devices, which was acquired by Medtronic. He also was the president of OrthoWin, acquired by Zimmer-BioMed. He received a B.S. in physics and an M.S. in chemical/biological engineering from the University of Colorado, and an M.B.A. from the University of Phoenix. He can be reached at jim.kasic@boulderiq.com or on LinkedIn.

Peggy Fasano is Chief Operating Officer at Boulder iQ. She is an expert in product development, project management, and engineering within the medical device and biotech industries. She has held the positions of senior consultant with Deloitte Consulting, managing director of the Deming Center Venture Fund, product development and engineer consultant for Boulder BioMed, and project manager and mechanical engineer for Sophono, Inc. She also has worked as a mechanical engineer and project manager at Polestar Technologies. Fasano holds a B.S. in mechanical engineering from Tufts University, and an M.B.A. from the University of Colorado. She can be reached at peggy.fasano@boulderiq.com or on LinkedIn.

May 2021

Boulder iQ
Innovation to Quality

Boulder
Sterilization

Contact Us

Boulder iQ	Boulder Sterilization	Boulder Medical Device Accelerator
Regulatory, Quality Engineering, Manufacturing, Packaging	Ethylene Oxide Contract Sterilization	Medical Device Startup Accelerator

Keeping Perspective...

We help clients remember their goals through the product development process, whether that is the next investor milestone or market launch.

Peggy Fasano, COO of Boulder iQ

Contact us

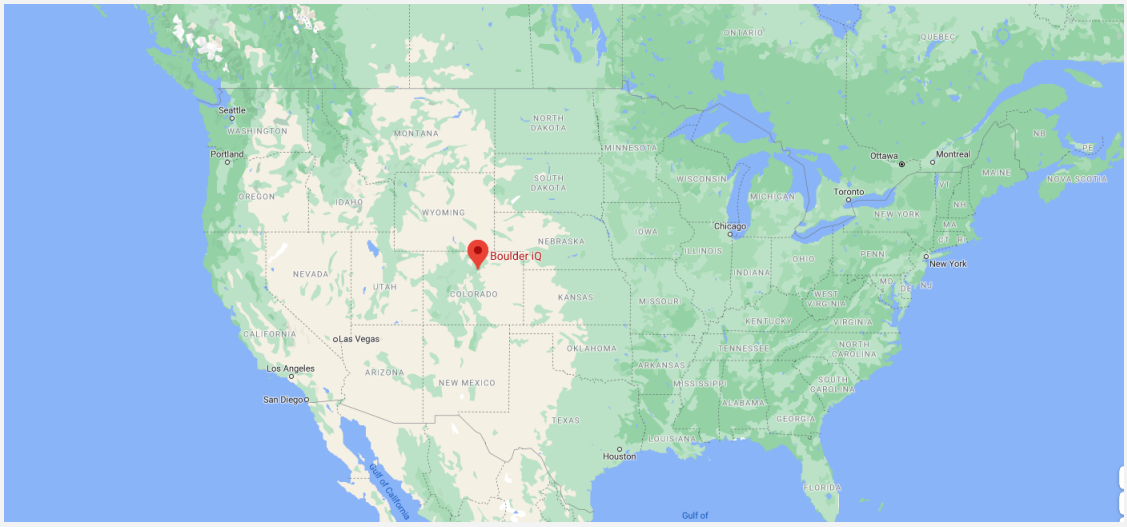
(303) 531-1238
5421 Western Ave.
Boulder, CO 80301
info@boulderiq.com

Opening hours

Mon - Fri:
8:00 am to 6:00 pm

Practice Areas

RA/QA
Product Development
Manufacturing/Packaging
EO Sterilization



Follow Us on Linkedin
(303) 531-1238
info@boulderiq.com
Boulder iQ | Boulder Sterilization | BMDA