Boulder iQ
Innovation to Quality

Boulder Sterilization

RA/QA | Engineering | Manufacturing | Sterilization

About Us:

Boulder iQ and Boulder Sterilization offers full-service medical device engineering development & manufacturing firm with regulatory affairs, clean room assembly and on-site EO sterilization. Boulder iQ and Boulder Sterilization focuses on the most efficient processes for the best possible "time to market."

From the Desk of Founder: Jim Kasic

We have some very nice conference rooms here at Boulder iQ, and they're essentially brand new. Our new headquarters building was ready for occupancy in mid-March of 2020, so with great enthusiasm we moved into our new digs to begin another great year. But you all remember what happened in March of last year.

So throughout the pandemic, our lovely new conference rooms sat essentially unused...

Read more below

In this Issue

We take a look at a variety of topics: how *3D Printed Models Can be Misleading,* the *FDA's Breakthrough Devices Program,* the second part of *Early-Stage Medical Device Valuation Strategies*, the importance of *Designing Packing for Sterilization*, and the announcement of a new addition to the Boulder iQ team!

3D Printed Models Can be Misleading

How Pareto's Principle is commonplace in the coalition of medical devices and 3D printing, and how to address some of the problems it creates

Read More

FDA's Breakthrough Devices Program

What the effect of the FDA's Breakthrough Devices Program has on the medical device industry and how patients and sponsors both can benefit

Read More

Valuation Strategies for Early Stage Medical Device Companies (Part 2)

The second article in a 2 article series about how to build value in your company step-by-step to attract funding and turn your entrepreneurial dreams into reality

Designing Packaging for Sterilization

The importance of designing safe and cost-effective packaging for terminally sterilized devices, taking into account the packaging design for shipping, transportation, storage, and end use of the product.

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Read 'Part 1' here

Addition to the Boulder iQ Team

We are pleased to announce the recent addition of Larry Blankenship to the position of company Director at Boulder iQ. A lifelong executive and entrepreneur in the medical device industry, Mr. Blankenship earned his Bachelor of Science from Arizona State University's College of Engineering and has since been heavily involved with many successful start-up companies. Mr. Blankenship's distinguished ability to lead others combined with his vast knowledge and experience of the medical device industry will add great value to Boulder iQ's plans to evolve in the medical device contract manufacturing industry.

September 2021

Read more about Larry's hire

From the Desk of Jim Kasic (cont.)

Jim Kasic M.B.A., CEO & Chairman, Boulder iQ, Boulder, CO

...

I like Zoom. It's a valuable tool, and certainly a great way to keep in touch with clients, especially as we move quickly through their projects. But it's not a substitute for in-person connections. Within the past week, we've held meetings *in-person* in our still new, but now over a year older conference rooms. What a difference!

I've heard that a large percentage of communication between people is non-verbal. Call it body language, facial expressions or whatever. On the telephone I can get some information from the tone of a person's voice. On Zoom, I get more information from their facial expressions, or perhaps the way they're sitting in their chair, if the view allows that. But when I'm in the room, present with other people, I can *feel* them! There is no substitute when establishing or renewing a personal connection. And I believe all business connections are also personal.

Boulder iQ and Boulder Sterilization are *service* businesses. We succeed by guiding and helping our customers succeed. They rely on us – our experience, our insights, our diligence, and our focus on meeting *their* needs above our own. This is why we do what we do. And now that we can again host our clients, our *friends*, in person, we're doing as much of that as possible. Please visit us! There's nothing like the warmth of a smile in person – a handshake (or elbow bump if you prefer) – but face-to-face. I'd love to meet you or see you again! This is my personal invitation. Hooray for 2021! Let's move forward to accomplish great things together!

Sincerely,

Jim

3D Printed Models Can be Misleading

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

Things are really cookin'! Your startup got some seed funding a few months ago and your product concept is taking shape. A few quick concept drawings in a 3D drawing package, send the file to a 3D print shop (or your own 3D printer) and voila! You take your shiny new 3D model to your investor meeting and what a reception you get: "Wow, that's amazing! Let's go to production immediately!"

Oops. Whether or not your investors or you realize it, you have just run into a wall. The train's going off the cliff, and the expectations you just raised are not likely to happen.

There's a concept called Pareto's Law, or Pareto's rule of 80/20. Interpreted for start-up medical product companies, "It will look like you're 80% of the way done, when you're really only 20% of the way done." The availability of 3D printed models has just made Pareto's Law a lot more commonplace.

A great-looking concept model is a terrific milestone as long as it's taken in the proper context. If you're developing a medical device, you still have a long way to go. If your audience for the presentation, such as your investors, doesn't understand this and its implications, they'll naturally think you're close to production due to the finished look of the model. This lack of understanding can easily turn into disappointment and frustration, and lead to some very unpleasant consequences in the future…one of which could be you possibly losing your job!

The good news is that there are ways to place things in context, and potentially to actually get a bit closer to a producible design, by planning ahead. Here are some pointers:

- Communicate the realistic likely schedule – with contingencies and iterations – before your presentation meeting.
    - Establish realistic expectations from the beginning, and don't let your audience get carried away with the "look" of a good model.Plan on things going wrong along the way and have alternatives identified.

    - Put iterations into the schedule from the start. As much as you'd like to think you'll get it right the first time, it almost never happens.

    - Build in time to meet the regulatory requirements, such as obtaining user input, performing risk and hazard assessment, developing design controls, conducting design reviews, building a Design History File (DHF), conducting verification and validation testing and standards compliance testing, and transferring to manufacturing (including the DMR, the Device Master Record). For more on how to streamline this process, check out the Boulder iQ article on "Eliminating the Gate in the Phase-Gate process."

3D printed models are a great tool for trying out different aesthetic approaches or for human factors studies. Several variations can be made quickly for usability engineering sessions (e.g., focus groups) before finalizing the design. But make sure the audiences know they're only for early-stage testing.

It's common to want to go into production with 3D printed parts. There are several issues with this idea for medical devices, though.

- If this is a sterile product that will come into contact with the patient, it must be shown to be biocompatible per ISO 10993. This is typically an expensive and time-consuming process, and not all 3D materials will pass these tests.

- If you qualify a 3D printed product for biocompatibility and then switch to injection molding later, you'll most likely have to repeat biocompatibility testing, as it will usually be a different material and a different process.

- 3D printing is a quick and relatively inexpensive way to make a small number of parts, but is not economical for higher volumes. Will you need quantities of 10, 20, 30? Sure, 3D print 'em. 100? Maybe. 1,000? 10,000? Probably not.

- If you're printing an enclosure for a product that will contain electronics, the material must meet standards for electrical and fire safety, and not all 3D printing materials will qualify. Performing the required testing is expensive and time-consuming, so it usually makes sense to do this only on the final component configuration (i.e., materials certified to UL 94-V0 or equivalent standards)

You'll want to perform Design for Manufacturing (DFM) before you go into production. You might want to consider this for the model you 3D print if you're sure enough of your design approach. Take into account these factors:

- 3D printers can print almost *anything*. That includes parts that have undercuts which could never be released from a production injection mold, and shapes that can't be reproduced by any other means than 3D printing.
- If you're confident in the size and look of your design, you can:
    - include tolerances and manufacturing considerations into the file you print;
    - design for moldability by employing drafts and uniform wall thicknesses in the design;
    - perform GDT (Geometric Dimensioning and Tolerancing) techniques and worst-case stack up calculations to be sure you'll get interchangeable parts;
    - sometimes accommodate material shrinkage in the 3D printed models if you choose the right materials and adjust your design accordingly.

Pareto's Law has always been with us. 3D printing just makes it more commonplace. 3D is a great tool for quick models and to test concepts, but don't let it get you in trouble. That old adage is still true: People don't plan to fail; they fail to plan.

September 2021 [Read this article on our website]

FDA's Breakthrough Device Program

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

To its credit, the FDA has developed a number of programs to increase, or speed, the availabilty of medical devices, drugs, and biologics under special circumstances. The Orphan Product Designation grants special status to a drug or biological product to treat a rare disease or condition. Emergency Use Authorizations during Covid are another example. The Humanitarian Use Designation for was developed for devices intended to treat or diagnose a disease or condition that affects of is manifested in not more than 8,000 individuals in the Unites States per year.

Another such FDA program worthy of note is the Breakthrough Devices Program. This program is intended to expedite the approval of devices an device-led combination products intended to treat critically ill patients. The Breakthrough Devices Program implements section 360e-3 of the Federal, Food, Drug, and Cosmetic Act (FD&C Act). The stated purpose of Section 360e-3 is:

§360-3. Breakthrough devices
(a) Purpose
The purpose of this section is to encourage the Secretary, and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the Food and Drug Administration's review of, devices that represent breakthrough technologies.

Although the Breakthrough Devices Program was initiated in 2017, the concept was in place, in one of three programs, as early as 2011. The Innovation Pathway (IP) was piloted in 2011. The IP was established to facilitate the development and create a priority review program for pioneering technologies. The IP pilot was later ended. The Priority Review Program (PRP) which was implemented in 2013 established priority review for medical device premarket submissions and was structured to realize efficiencies in the review process. The expedite Access Pathway (EAP) was launched in 2015. The EAP was an expedited market access program for certain high-risk devices targeting life-threatening diseases or ailments. Both the PRP and the EAP were replaces by the Breakthrough Devices Program. The current Breakthrough Devices Program incorporates elements of all three of the previous FDA programs.

The Breakthrough Devices Program is a two-step process. The first step is the Designation Request. The second step is the actions the FDA will take to speed the development of the device and give the device priority in the submission review process.

In order to be disgnated as a Breakthrough Device, a device mnust meet the following criteria, as stated in Section 360e-3(b) of the FD&C Act:

(1) that provide for more effective treatment or diagnosis of life-threatening

or irreversibly debilitating human disease or conditions; and

(2) (A) that represent breakthrough technologies;
(B) for which no approved or cleared alternatives exist;
(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or esablish long-term clinical efficiencies; or
(D) the availability of which is in the best interest of patients

In this Designation Request step, the device sponsor requests that the FDA designate the device a Breakthrough Device. A Designation Request is submitted as a Q-Submission must include a device description, the indications for use, the regulatory history of the device, and the regulatory pathway the sponsor intends to pursue, i.e., PMA, De Novo Request, or 510(k). And most importantly, it must also demonstrate how the device and its indications for use meet Criterion (1) and one of the four elements of Criterion (2).

Once a device is designated as a Breakthrough Device, the specific features of the Program begin:

- Interactive and timely communication
- FDA consultation with external experts or an FDA advisory committee
- Postmarket data collection
    - allowing for postmarket data collection to speed the development and review of the device
    - accepting more uncertainty in the device risk-benefit profile provided it is balanced by other factors
- Efficient and flexible clinical study design
- FDA review team support
- Senior FDA management engagement
- Priority review of all submissions
- Manufacturing considerations for PMA submissions
    - less QMS manufacturing information if certain requirements are met
    - in certain circumstances, deferring the manufacturing site inspection for as long as 12 months after the device has been approved

The Breakthrough Devices Program has become increasingly popular, with more sponsors taking advantage of the Program each succeeding year. A study

by Johnston et al.[1] found that as of January 1, 2020, the FDA had granted 248 Breakthrough Devices and approved PMA's pr cleared 510(k)'s for 15 Breakthrough Devices. Through May of 2020, there had been 298 Designations[2]. The breakdown is as follows:

Time Period	Designations
Prior to Dec 13, 2016 (EAP)	26[1]
Dec 13, 2016 - Dec 31, 2018 (EAP and BDP)	84[1]
Jan 1, 2019 - Jan 1, 2020 (BDP)	138[1]
Jan2, 2020 - May 27, 2020 (BDP)	50[2]

The Breakthrough Devices Program is beneficial both to patients and to sponsors. It offers the advantage fo FDA advance agreement on issues such as clinical trial design and date to be collected so that there are no surprises in the review process. The flexibility built into the Program and the FDA support and input invaluable. Frequent interaction with the FDA is also an advantage due to the information it provides. The sponsor and the FDA have formed a partnership, as it were. Both parties are heavily invested in making the device available to the patients who need it.

[1] Johnston, J.L., Dhruva, S.S., JS Ross, J.K., and Rathi, V.K. Early experience with the FDA's Breakthrough Devices program. Nature Biotechnology – nature.com (2020)

[2]starfishmedical.com/blog/fda-breakthrough-devices-program/

September 2021 [Read this article on our website]

Valuation Strategies for Early Stage Medical Device Companies (Part 2)

By Larry Blankenship, Director, Boulder iQ

Step 4: Find Comparables – Learn From Them and Use Them

Who else has something even remotely similar to what you are doing? Did they exit in a merger or acquisition? How similar was their enterprise to yours? What comparisons can you make?

I was part of a company making a new surgically implantable heart valve. We had a unique technology with specific advantages. There was a history of innovative heart valve companies, however, using different technologies. That history provided us a road map regarding how much money was invested before they were able to commercialize their products before they reached break-even and attained positive cash flow. We also knew how much their company sold for in an exit to a larger company. This analysis gave us some good perspectives for dealing with potential investors on how much to raise, what timing to expect and how much our company might we worth at an exit event.

Step 5: Make real, tangible progress

Talk is cheap. Don't expect to be funded after your first presentation to a prospective investor.
Watchful waiting is a common and effective strategy for investors at all levels – they have the money and the time to see what develops. They'll be watching your progress and monitoring your ability to do what you say you're going to do. This is part of the due diligence process in most cases.
By working hard and diligently over time, and showing REAL, TANGIBLE progress in achieving your milestones (and beyond), you'll gain their respect, their confidence, and increase your likelihood of receiving a term sheet. Even if you don't have much money, there are things you can do to build on your story, attract additional supporters, and show how your invention will capture the sales you believe it can. Don't waste time! That's a sure way to turn off investors.

Step 6: Get the Word Out

There are startup companies that operate in "stealth" mode and keep their progress to themselves. This has the advantage of not letting your competitors know your real state of development, but it can only be done if you have a committed investor who supports that approach. Otherwise, you need to let your potential investors and partners know of your activities and successes. Step 2 is key to being able to execute this step. If your ideas are well protected with broad patents or patent applications, full of blocking strategies, then get the word out!

You'll be developing a short list of potential investors who have expressed interest in keeping in touch. So keep in touch! Let them know of your progress on a regular basis, e.g., monthly. Professional investors see hundreds and hundreds of companies in a constant flow of applications. You need to remind them about your company – and the more frequently they see real progress from you, the closer you are to a serious investment discussion.

Be careful not to "bug" people with meaningless emails, however. That will have the opposite effect. But when anything significant happens, broadcast it to your limited network (individually – don't let investors see who else you've engaged). If you get a patent allowance, if you are awarded a grant, if you succeed at an important test or animal lab, if one of your medical advisors presents at a prestigious meeting – let people know. And don't be afraid to ask for a meeting to discuss your progress and next steps when you feel it's appropriate.

Press releases about key accomplishments, awards or new hires are a good way to get the word out. Post them on LinkedIn, and make sure you're constantly increasing your LinkedIn network (I'm over 3,000 now and growing). Another way is to publish a periodic newsletter if it's *interesting*. It needs to demonstrate your company's knowledge and leadership. The readers should take away key points of interest, be pleased that they took the time to read it and be looking forward to the next newsletter.

Step 7: Build Key Relationships

People invest in people! The person who spearheads getting you a term sheet is your champion. That person is betting their personal reputation on you and your company. They're entrusting YOU to work with them and achieve success so they will rise in the eyes of their peers. It's a personal win-win proposition. So be bold, but also conservative enough so you truly believe you'll succeed and won't let your champion down.

Get to know your audience. Find out about the investment firm you're approaching. Don't waste their time or yours if it's clear from their website and portfolio that you're not a fit. When you find a firm with a good fit, find out about the people you'll be dealing with. What's their background, their investment history, the companies they've promoted, the boards they serve on, the exits they've had, their technology specialties and perspectives. If you expect these people to be your partners, you'd better get to know them. It's important not only to achieve a term sheet and an investment, but for the long run as well. After all, this firm and these people are going to own part of your company.

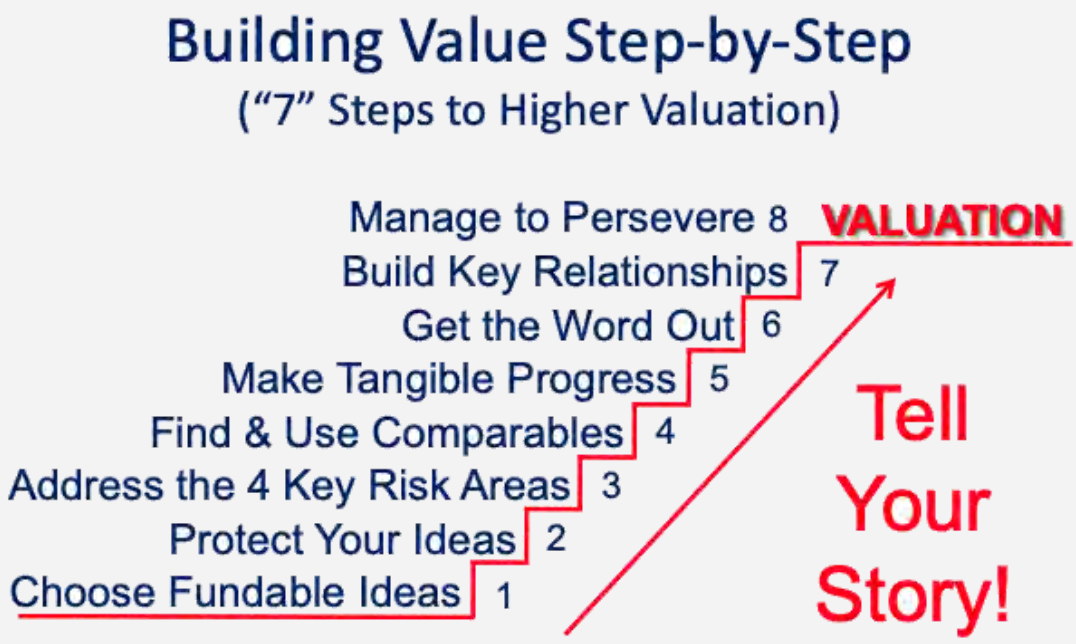
Eventually, you will probably have a minority share – that's typical due to the significant funding that's necessary to bring most medical devices to market. These early investors will sit on your Board of Directors and have a lot of influence. You need to see eye-to-eye philosophically and practically. You need to be able to work together as friends and colleagues. Taking money from an organization or people who don't have your friendship and trust can become a nightmare. Of course the money's important now, but at some point that money will be spent. New money will come in, and you'll be left with the people and the relationships. As hard as it may be, you may need to wait in order to take money only from people you trust and with whom you can work amicably.

Other relationships that are also critical to your success:

- Your day-to-day business partners and colleagues
- Your Board of Directors
- Your Medical and Scientific Advisors
- Other Business and Technical Advisors

Your success hinges on your wisdom to listen to good advice and take it. Sometimes we get in our own way based on impetuousness, naivete or stubbornness. This can be disastrous. I've had experience with extremely learned scientists, brilliant people, who believe they can short-cut the business process only to wind up bankrupting the company. In the end, success comes from making sound business decisions based on good advice from experience business professionals. Listen to your advisors!

The 7 Steps Graph:



The 8th Step: Manage to Persevere

In order to thrive you must first survive. This means doing whatever it takes to keep your business alive long enough to get funded. You may have to go long periods with little or no salary, as may your colleagues. Such sacrifice is not only necessary but is also noticed by potential investors and is an important factor in their investment decision. Early company funding typically comes from your personal savings, support from friends and family members, and many times a good credit rating. I've run my credit cards to the max and had to take a second or third mortgage to survive. Sometimes it's paid off. Sometimes it hasn't. Only you and your family can decide if you want to take the risk to start a company. And it IS a risk. Being an entrepreneur is not for the faint of heart. You very well may find yourself broke and starting over –

possibly through no direct fault of your own. At that point, you can give up, or learn from your mistakes and get back in the saddle. It's up to you. Perseverance, determination, tenacity and intestinal fortitude (i.e., "guts") are prerequisite requirements to being an entrepreneur. Get tough and stay tough, or don't start. It's not for everyone. But if you do proceed, you'll find out things about yourself you've never known. You'll become a broader, more experienced, wiser person, leader and role model. And if the financial rewards aren't there at first, those *are* your earnings. Despite some setbacks, I've found them well worth the effort. I hope you do as well.

And at long last when you do get the money – *don't spend it*! There's a sigh of relief to have money in the bank. You envision all those things you've been waiting to purchase, the additional amounts you'd like to put in your pocket and those of your colleagues. Be smart! You're still a startup, you're still "going broke" a little bit at a time. Until you have revenues and positive cash flow, pinch those pennies – take more in equity and less in cash. You company's life depends on it.

Overall, make sure you're having fun as well! Starting a medical device company is a great adventure, but if it's not the right adventure for you, then do something else. If this is your calling, however, then go for it! You'll find it grueling, exhilarating, frustrating and rewarding. And the world will be better for your having done it! Creating a fundable company is a combination of the right project, team, business model and market. Remember to keep all these aspects in sight as you start or continue your journey. And follow the 7 steps to increase your valuation – it's a critical part of the process!

A final note: I recently found a company and its technology so appealing, I jumped in to help. Startup number five! So . . . here I go again!

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

larry.blankenship@boulderiq.com

September 2021

Read this article on our website

Designing Packaging for Sterilization

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

INTRODUCTION:

Packaging is one of the last stages of the design and development process for a terminally sterilized medical device, despite it being at the end, it is a critical aspect of the design. Packaging keeps the product sterile and safe prior to use. A terminally sterilized medical device is a product that has been exposed to a sterilization process in its sterile barrier system to reduce disease transmission by killing viable microorganisms, they must follow ISO 11607: 2019 *Packaging for Terminally Sterilized Medical Devices*.

The packaging is what keeps the product sterile and functional after the sterilization process, shipping, transport and storage. Packaging is required to go through several different validation studies to ensure that the packaging system works properly including a shelf-life study and a shipping/distribution testing. This article will be focused on designing packaging for sterilization to ensure you are optimizing the sterilization process and the product packaging.

PACKAGING DETAILS

The medical device packaging typically includes several layers of protection for a product. The product is put on a tray or backer card then the lid is sealed or is put into a pouch and sealed shut. The pouch, depending on the type of sterilization, may have breathable material to allow for proper sterilization. This pouch or lid is what keep the product sealed and sterile after the sterilization process.

<insert picture>

Once there is a sterile barrier system such as a pouch, product is typically placed in a carton. Then a certain number of cartons is placed in a shipping box. This entire design is considered the packaging system. Labels will need to be on the pouch, carton and shipping box.

Designing the packaging should start earlier than you may think. There are many different factors that play into the design of the packaging including sterilization, shipping and the end user. During the entire design process, keeping the end goal in sight is very important. The packaging should be safe, cost-effective, and readily available. Packaging materials should never be the

thing holding up market launches or product shipment.

DESIGN FOR STERILIZATION

There are two main aspects to consider when designing for sterilization 1) determining what type of sterilization is required and 2) what are the product volumes at market launch and beyond.

There are four main types of sterilization: Ethylene Oxide, Gamma, E-Beam and Steam. Ethylene Oxide is a great method known for its low temperature and compatibility with all plastics and metals. Gamma and E-Beam both use different irradiation methods and is compatible with most materials but can cause discoloration and brittleness in some materials. Steam is used mostly in a just-in-time manner at the hospital, it works well with metals but no other materials due to the high temperatures and humidity. Currently, Ethylene Oxide makes up more than 50% of the industrial sterilization in the US because of its compatible with nearly all materials and efficacy.

The amount of product that will need to be sterilized at a time will affect the decision of what type of sterilization. Product is regularly sterilized in pallets; however, there are some growing options for smaller volumes. Gamma and E-beam require large amounts of product, think pallets, Ethylene Oxide varies from small chambers of 8 cubic feet to truck loads at a time. Steam sterilization is typically low volumes and completed at the hospital. Ethylene Oxide can be the most flexible option as the chamber sizes vary the most. Small chamber Ethylene Oxide can be a great choice for high value products, modest volumes, small sized products and R&D work. Starting with a company like Boulder Sterilization which has smaller chambers can give you an advantage with quick turn around and less up-front costs.

Once a sterilization method has been chosen, the type and size of the packaging can be chosen.

Depending on the type of sterilization that is chosen for the product, the packaging will need to be different. For example, Ethylene Oxide requires a breathable material such as Tyvek to be a part of the packaging to allow for easy entrance and exit of the gas into the package and product. Gamma and E-Beam require slightly different packaging configurations. Steam requires a similar pouch to Ethylene Oxide. All pouches or lids need to fully seal the product in the package so no molds, yeasts, viruses or bacteria can find their way onto the product.

The size of the packaging can affect the cost of sterilization significantly. Contract sterilizers deal with set chamber constraints. Designing the packaging to these constraints can optimize the amount of product you can fit into one sterilization run and reduce production costs down the road. I recommend always reaching out to sterilization vendors first to understand their chamber sizes while designing the packaging. For example, if you have 2 inches of extra space on the edge of a pallet that is unused space that adds up in cost. For smaller chambers, this is especially important since the amount that can fit into the camber could change in an order of magnitude. Here at Boulder Sterilization, we try to emphasize the best practice of design the packaging with space utilization in mind. If your packaging can be smaller, the more product you can fit in the sterilization chamber reducing costs.

Designing the packaging with sterilization in mind will save you time and money in the end by ensuring the packaging will keep the product sterile and

optimizing the space available. We have had clients in the past who chose to go with E-Beam, then found out that their product will not work with E-Beam, had to redo all the packaging and switch to Ethylene Oxide.

OTHER DESIGN ASPECTS

There are certainly other aspects to consider when designing packaging. The packaging should keep the product from damage during shipping and transportation, there are plenty of questions to consider. What will the typical mode of transportation be? Does it need to fit in a custom shipping box or would a Fedex box work just as well? Would you ever want to ship in different configurations? In addition to shipping, understanding the typical storage conditions is also important. Will the product ever see extreme temperature or humidity in storage? Do you need to constrain these conditions? How long does the product need to be able to sit on the shelf?

Not only designing for sterilization and shipping/storage is important but also, designing for the end user. Who will be using the product? Will they be concerned more about the function or look of the packaging? Is it going to be sitting on a hospital shelf, what size if the shelf? Does the end use have access to recycling or large trash cans for additional packaging materials? Does it need to be double pouched? These are all additional considerations that should be thought of during the packaging design and just as important as the product itself. If an end user can't open the package in an efficient manner, their satisfaction will decline.

CONCLUSION

It can be difficult to weigh and rank all the aspects that go into the packaging for a sterile device. Making sure to design the packaging upfront is any easy way to save time and money. By figuring out the sterilization needs and vendor concurrently with the packaging design, along with thinking of the shipping, storage and end user can create a great packaging system that will work with a stake holders.

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Innovation to Quality

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

Manufacturing,
Packaging

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

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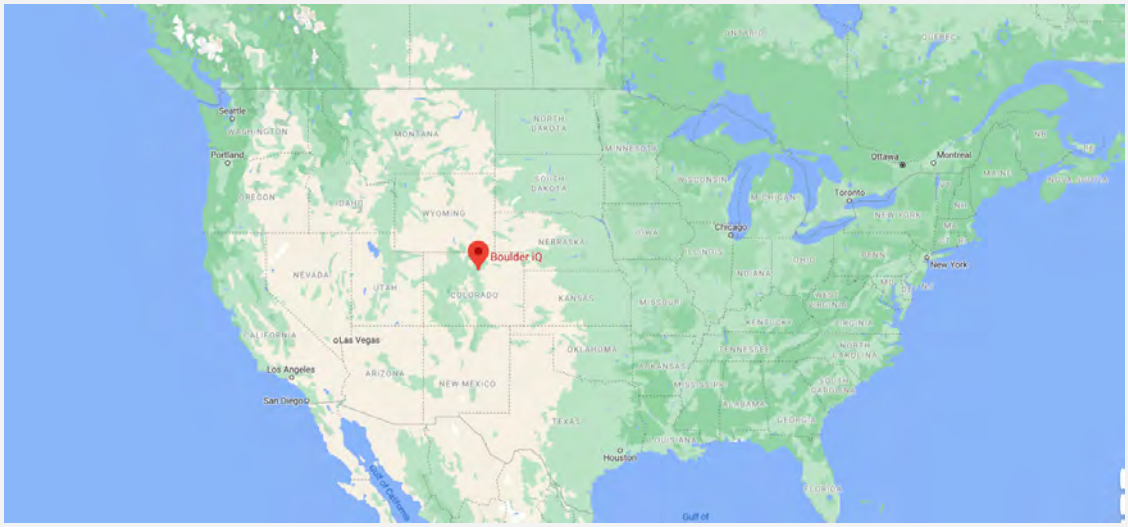

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