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 focus on the most efficient processes for the best possible "time to market."

From the desk of Jim Kasic:

Second Sourcing EO Sterilization Services

Prevent supply chain logistics from getting in the way of your next product release, be ready for the unexpected and second source your EO sterilization needs today.

Read more below

In this Issue

We take a look at a variety of topics: Second sourcing EO sterilization, Med tech decision making, How "Great" can be the enemy of "Good", and a Guide to surviving FDA inspections!

Is it a Business, Engineering, or Regulatory Decision?

Which field of expertise is needed for medical device decision making? The answer might surprise you.

Read More

Great is the Enemy of Good – Be Smart with your Startup!

Focus on your Minimally Viable Product, get a reliable device to market quickly, and build your reputation.

Read More

How to survive an FDA inspection, Part 1

Learn the ins and outs of FDA inspections and how your company can avoid future regulatory and quality pitfalls.

Read More

From the desk of Jim Kasic: 2nd Sourcing EO Sterilization

Jim Kasic, Founder and Chairman, Boulder iQ and Boulder Sterilization

I'm a pilot. My son and I flew to the Sawtooth Mountains over Labor Day to do a 4 day backpacking trip. The air strip that we landed on is only accessible by plane, foot or horse. If anything went wrong, we were going to be in trouble. In preparing for the adventure, I checked and rechecked all the systems of the plane and every piece of our camping equipment.

Everywhere possible we had redundant backup equipment including socks, radios, water purification, smart phone batteries and chargers, etc. On the first day, while hiking into one of the alpine lakes and feeling the weight of the backpack, I started thinking "am I carrying too much, not enough", "did I bring the right things", and "how would I pack differently next time".

Of course, no matter how hard I tried to unplug from work, my thoughts wandered back to the office and I started thinking about one of Boulder

Sterilization's clients. This particular client approached us in a panic. They had 8 pallets of product sitting on the dock of their contract sterilization facility since before Memorial Day. Our client's contract facility had been overwhelmed with the sterilization demand and to add insult to injury was short staffed due to the pandemic.

Prior to COVID hitting in early 2020, the biggest medical device concern from the FDA was the US capacity to Ethylene Oxide sterilize the US supply of medical devices due to several large sterilization facilities closing.

As the old saying goes "if you put all your eggs in one basket, watch that basket". The first rule I learned as a young engineer was to second source all critical components and processes. One of the worst things to happen to a successful company is to have customers but no product to sell them because the supply chain broke down.

How many companies have more than one sterilization contractor? I'll bet you, not many. This brings up the question of second sourcing your sterilization.

Boulder Sterilization offers "quick turn" sterilization validations and continues to add sterilization capacity to meet the market's growing needs. Because our chambers are small, they have short cycle times and allow for 4-day turn around times (a day to receive the product, a day to sterilize, a day to ship and an extra day in our estimate – just in case).

It's always better to have a second source before you need one. Contact Boulder Sterilization to see how we can help to de-risk your supply chain.

Sincerely,

Jim

December 2021

Read this article on our website

Is it a Business, Engineering, or Regulatory Decision?

Larry Blankenship, Director, Boulder iQ and Boulder Sterilization

Is it an Engineering, Regulatory or Business Decision?
After being in the medical device industry for over 30 years and consulting for hundreds of clients over the last 10 years it's amazing how often medical device developers get confused about what kind of decisions they must make;

Engineering, Regulatory or Business decisions. I have seen many moments where a startup is thinking a decision is one of these categories but is actually another. It is important to discern what type of decision is being made and the effects on the other two categories. All three can easily and naturally effect the others. In this article, I explore examples of many different decisions that a medical company need to make.

Regulatory Decisions in Disguise

The easiest, but least understood decisions are regulatory and quality decisions. Many decisions during product development and after-market release will affect regulatory and quality, it is woven throughout an organization. However, there is a silver lining in that regulatory bodies (FDA and EU Notified Bodies for example) try to be very clear on how to obtain regulatory clearance or stay compliant. When circumstances are not clear, the FDA has mechanisms (513(g) and Q-Subs) to gain clarity on the path for regulatory clearance. Once your product is on the market, there will likely be regulatory and quality issues that arise in the case of proposed product changes, for example. Will a proposed change require submitting an amendment to the 510(k)? You don't have to guess. The FDA provides guidance documents and decision flow-charts to allow you to arrive at the correct answer.

Business or engineering decisions can turn out to be regulatory decisions depending on the impact of the change.

For example, in order to lower cost on a single-use sterile disposable product, the company decides to move production to Asia. What are the regulatory implications? First, realize that the company is always responsible for making sure that its products are safe and effective and perform as claimed. Period. No matter where they're produced. Depending on the class and risks associated with a specific product, the manufacturing and sterilization facilities may need to be inspected by the FDA even if they are outside the USA proper. This business decision of moving production has regulatory side effects, understanding the implications of the regulatory impact could affect your business decision.

In another example, let's say the integrated circuits are outdated and your company decides to redesign to use more reliably available components and to lower manufacturing costs. From a "black box" perspective, the circuit cards perform the same functions as they did previously and the overall product intended use and claims are unchanged. This is an engineering decision to redesign with more available components and a business decision to continue production and reduce cost, but what are the regulatory implications? Again, refer to the FDA Guidance Document referenced above and perform risk assessments per ISO 14971 along with re-doing applicable Verification and Validation (V&V) testing and documenting the results as a minimum prior to releasing the change. Retesting to confirm compliance with standards such as IEC 60601-1 will also likely be required. Regulatory and quality considerations will be present in most decisions but the regulatory bodies try to make it clear what actions you need to take to stay compliant.

There are times that a business and a regulatory decision and perspective are

extremely intertwined. Startup founders commonly don't understand the regulatory implications for the medical indications for use. These are significantly different domains. From a regulatory perspective, therapeutic claims and "Indications for Use" need to be relatively narrow. Every claim made in this context must be backed up by evidence and authorized by the FDA through the 510(k) or other process. For example, if you have a technology that was designed for hip surgery but can, say, be used in shoulder, knee, and hip surgery. The regulatory body will require evidence that indeed the product works in each of those scenarios. This has now likely tripled the amount of testing you will need to do. Also, be careful about using claims that doctors might make for your product in peer-reviewed or other publications or presentations. The doctor can say something like "I've cut my patients' hospital stay time in half with this product!" Great! You can suggest that people read the doctor's article, but you can't make the claim yourself without adequate evidence and FDA authorization.

Quality Decisions: Black and White

Decisions regarding manufacturing process issues can be confusing as well. I once found a young quality engineer who stopped production and was ready to write a CAPA because the new batch of product had one dimension that was slightly bigger than the last batch. When confronted, I asked if both batches were within the specification and passed QC testing. The answer was yes. I also asked if the new batch, being larger, increased any risk to the patient. The answer was No. So why was production stopped? Because "something was different". Medical device manufacturers need to live by their specifications. The product is either "in spec" or "out of spec." That being said, it's always appropriate for a production worker to raise an issue or ask a question.

Another example was a company who was selling product faster than they could make it. They asked me to take a look at their processes. It was very clear that they were using bench top operations to manufacture, just like they did during the research phase. These processes couldn't scale. When presented with higher volume processing techniques the QC team got stuck asking "how do we know the product in is the same using the new technique?" The answer is simple, "Did it pass the specification and QC test?" If yes, then it is the same. The problem was that this company did not have good specifications, process validations, or QC tests for each step in their manufacturing process. We put those in place and the questions disappeared, the answers were obvious in light of the new specs and procedures.

Engineering Decisions

The next set of decisions to make are the engineering decisions. Short of "unobtanium," almost any device can be designed, tested and built to obtain regulatory clearance given enough time and enough money. But not all engineering decisions are good business or regulatory decisions. Engineers need to have not only the product requirements and user needs in mind they must also be designing for a target manufacturing cost at pre-determined volumes so that the price of the product can compete in the marketplace. Having a regulatory strategy from the beginning of the design process is also important. The engineering team should have an outline of the key standards,

verification and validation testing that their design must meet. For example, if a sterile product requires a 5-year shelf-life claim, that consideration must be taken into account when designing the packaging.

Business Decisions

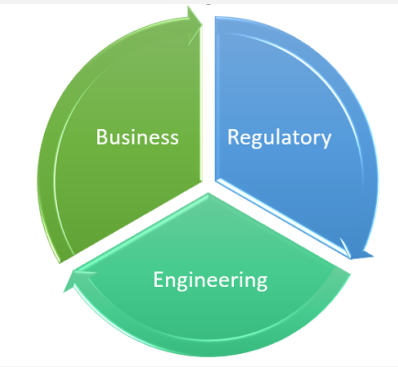
Finally, there are business decisions. Time and money are not infinite and typically are in very limited supply. Let's assume a product design, qualification and regulatory approval project will take 5 years. At the time of the start of the project, the market looks like it will be eager to receive the new device. A few years into the project, however, a new technology is introduced that dramatically impacts the market potential of the product under development. A business decision must now be made. Do we continue the project to completion, spending the additional time and money? Or do we stop the project and see how we might use what's been learned and developed in other ways?

A real-world example is a company I'm familiar with that developed a tissue aortic heart valve with replaceable leaflets. It was implanted in the traditional open-heart surgical way, but when the leaflets needed replacement, the exchange could be done using minimally invasive techniques. The market was excited about this idea. During the product's development and clinical trials, however TAVR (Transcatheter Aortic Valve Replacement) technology was approved, a much better solution for most patients.

Things change. The business team must constantly monitor the competitive landscape and adjust plans accordingly.

Summary

In summary, the medical device business involves a never-ending stream of decisions, most of them requiring trade-offs. Few are clear-cut, black and white choices. It's important to separate the issues to determine whether they can be addressed with a business decision, an engineering change or a regulatory adjustment. In some cases, all three might be involved. In all cases your company is responsible for evaluating all changes for safety and effectiveness and making regulatory submittal amendments as needed. Continued business success depends upon clear thinking and efficient execution. By seeing issues from these different perspectives, implementing solutions to problems can be done in the most efficient way possible.



Great is the Enemy of Good – Be Smart with your Startup!

Larry Blankenship, Director, Boulder iQ and Boulder Sterilization

Things are looking good! You've raised some money for your new medical device startup and are ready to take your idea to the next level – from a back-of-the-envelope notion into real product development. You know the process. You have a Quality System that will guide you in the Design Control portions, but you're not there yet. Your idea needs to be codified, worked out, refined into a real product definition, followed by requirement documents and specifications.

So, you start with your users. Very appropriate. Learn their needs, their procedures, their constraints, and limitations. You then work with marketing experts, perhaps members of your board of directors or advisors from your investors. Where are the market inflection points relative to product features and pricing?

OK, let's get the best and brightest minds to do focused ideation, i.e., brainstorming. That gives us a variety of expanded and different concepts to augment or maybe even replace our napkin idea. At this point it seems like the options and issues are expanding to a confusing level. And then there's the hazard analysis and risk assessment. Preventing the "what could go wrong" issue will create its own set of requirements.

Naturally, we all want the best. The Board wants the greatest return as quickly as possible. Marketing wants the most desirable product that will demand the highest margin, and they're ready to launch today. That product has all the bells and whistles, of course. *What's taking you so long?*

You're at a very critical juncture. Decisions you make regarding the product you develop can and will make or break your company.

A well-known best-selling business book is "*From Good to Great*" by Jim Collins. In this examination of what sets apart great companies from good companies he postulates that "Good is the enemy of great." His hypothesis comes from a detailed study of over 20 companies, looking at ones who made decisions that led to significant increases in stock value compared to those whose stock either stayed about the same or rose only modestly. He concluded that when new ideas, products and services are considered and developed, those companies that "settled" for a good outcome were outstripped by those who persevered in pursuit of a great outcome, a stellar, outstanding, market-changing product or service.

Sounds good at first, but what kind of companies were the subject of Mr. Collins' study?

The list of the 28 companies studied included Abbott, Upjohn, Circuit City, Silo, Fannie Mae, Great Western, Gillette, Warner-Lambert, Kimberly-Clark, Scott Paper, Kroger, A&P, Nucor, Bethlehem Steel, Philip Morris, R.J. Reynolds, Pitney Bowes, Addressograph, Walgreens, Eckerd, Wells Fargo, and Bank of America. What do these companies have in common? They're all established, profitable publicly traded companies. Most are household names. At the time, they were all on the Fortune 500 list.

Given that information, what kind of resources do you think those companies could put into a project striving for "great?" Vastly more that your startup has available, I'm sure. And what if, in pursuing their great new product they should fail? Most likely they could write the expenditures off the books and the company would continue to move on and prosper. If your project fails, however, you're out of business. Kaput!

In the context of a startup medical device company, Great is the enemy of good!

So, as you're sorting through all the user options, extra features, marketing requests and similar considerations, think about this goal: Define and focus on the MVP. Period.

What's the MVP? The Minimally Viable Product. The product that will take your idea to the marketplace focused on the minimal subset of features that will be accepted by the market as a first product. The minimal number of features to be designed, developed, tested, qualified, and manufactured. The minimal number of features to install, service and provide training for. The minimal approach for regulatory clearance.

Here are a couple examples.

A simple device was designed to sample saliva and fluids from the esophagus and place them in a stabilizing solution for shipment to a laboratory for analysis. This was a small, delicate device and sterilizing the device without damaging it was difficult. Much time and considerable money was spent trying to qualify and validate a sterilization cycle that was reliable without damage to the product. When asked the question "Why does it have to be sterile?" the answer was that the predicate device was sterile. Digging deeper, the probe continued. Why was that? The mouth is not sterile. In researching the history it was discovered that one of the uses for the predicate device was to detect the bacteria *h. pylori*, a causative factor in stomach ulcers. That was not a use for this device so after considerable time and expenditures the decision was made to require the product to by hygienically clean. It did not need to be sterile after all. This is an example of not understanding the parameters of the MVP and thus including an unneeded requirement.

Based on breakthrough research to improve the survival rate associated with CPR (Cardio-Pulmonary Resuscitation), a patient positioning device was

envisioned which would raise the patient's head during the procedure. This patient positioning device was one more piece of equipment for the first responder to carry, along with all the other equipment that was already over-burdensome. So the idea morphed into a multi-function product – one device that would include the patient positioner and incorporate other features to reduce the load. Such features might include a built-in AED (Automatic Electronic Defibrillator), a mechanical chest compression mechanism or other devices. Designing and qualifying the product to include such additional features would have taken significant additional time and money, so the MVP was determined to be the positioner itself in a custom carrying case with both handles and straps so it could be carried in most any manner the first responder chose. The benefits of the product were extremely compelling, so even though it was "one more thing to carry," it was added to the first responder's equipment ensemble. Other features will be added to future models.

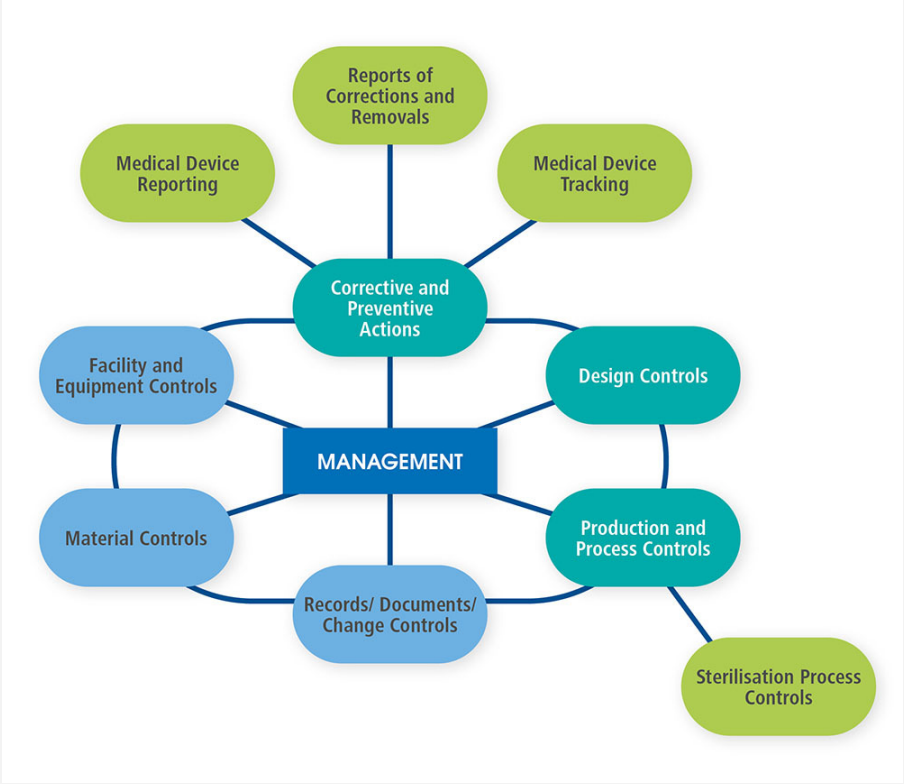
While you need to focus on a "good" rather than "great" product definition, getting the MVP to market as quickly and efficiently as possible, you want to make the design of the product excellent. Don't skimp there. Implement that MVP with care and attention to detail. Make sure it does what you claim it will do, every time, flawlessly, reliably. Enthusiastic acceptance of your MVP in the marketplace is your ticket to success. It establishes your new company's reputation – a reputation that will spread quickly among users. A good reputation will yield increasing sales. A poor reputation from a shoddy design will create hurdles that small companies may not be able to overcome. Make your MVP great, while staying minimal.

During the process, many temptations will emerge to alter your MVP trajectory. At market meetings, design reviews, focus groups and Board meetings you'll be asked about "just" adding this feature or that capability. You would be unwise to ignore such requests, they might be the one addition that will truly make your product sell and should be considered as part of the MVP. So, acknowledge such requests and consider them carefully. Use your wisdom, judgement, and wise counsel from your advisors to make your decisions, but also consult your bank balance and Gantt chart. Those two items will speak loudly as well. MVP! MVP! MVP!

In the end, focusing on a well-crafted, highly sought-after Minimally Viable Product will be the most achievable goal and the shortest path to revenues. Those revenues will allow you to attract more investments, develop follow-on, more feature-rich products, and eventually lead to positive cash flow and a self-sustaining company. And perhaps sometime in the future, you can say that "Good is the enemy of great" from your position on the Fortune 500! You have my best wishes! For now, please remember to focus on a high-quality MVP because "Great" truly is the enemy of good for your startup company!

December 2021 [Read this article on our website]

How to survive an FDA inspection, Part 1



Larry Blankenship, Director, Boulder iQ and Boulder Sterilization

It's a Friday, late morning or early afternoon. You're in the conference room with a few other executives of your medical device company. Also in the room is an inspector from the US Food and Drug Administration, the FDA. The inspector showed up the previous Monday for a scheduled inspection, which has taken all week. The inspector is now going to review the findings of the inspection.

How do you feel about this? Are you worried or concerned? If so, why? Or do you have a pretty high degree of confidence in your QMS and your people, and so you feel it will go well? There's no reason you can't be confident if you've properly prepared. The good news is, the FDA publishes documents that will allow you to do exactly that.

You have a QMS. Either you are using a commercially available software package, a QMS prepared for your company by a qualified regulatory consulting firm, or your internal team has developed its own compliant system. In any of these cases, the QMS has presumably been prepared with exacting attention to the detail needed for your specific company's operations.

So what can your company do to gain confidence? Perform a mock FDA inspection periodically and do it the way the inspector is going to!

How do I know what the inspector is going to ask or look for? Follow the same guidance documents that the inspectors use. The key ones include:

- Guide for Quality Systems Inspections (QSIT)
- FDA Compliance Guidance Manual - Inspection of Medical Device Manufacturers
- IOM - Complete Investigations Operations Manual

Study these documents, starting with the QSIT and establish a program to conduct periodic internal quality audits following these provisions. In other words, duplicate an FDA inspection periodically. Be appropriately critical of your own company and "write up" internal 483 like observations along with proposed corrective actions. Then follow up with those corrective actions and document there adequate completion.

Just behind the cover page of the QSIT, the FDA provides a diagram of the interactions between management and several operational aspects of a company following a Quality Management System. That diagram is shown above and redrawn for improved readability.

Below are several key items, common questions, and excerpts from the documents.

Q. Will the FDA just show up, or will they contact me in advance?
A. In almost all circumstances, especially for routine inspections, you will be contacted in advance and told when the FDA will come for the inspection.

Here's the excerpt on this topic from the IOM:

Pre-announcements are mandatory for all medical device surveillance inspections.

The pre-announcement should generally be no less than 5 calendar days in advance of the inspection. Should a postponement be necessary, the decision as to rescheduling rests with the investigator/team, but the new inspection date should not be later than 5 calendar days from the original date.

Q. Are there different kinds of inspections?
A. Yes. Here are some excerpts from the IOM.

1. Pre-market inspections (PMA, 510(k))
2. Foreign inspections
3. Instructed by Compliance Program, assignment or directive
4. Quality System Surveillance Inspections

Types of Inspections:

- Initial – first inspection
- Routine – normal surveillance inspection
- Follow-up – follow-up to a violative inspection
- For-cause – inspection to follow-up on a specific issue
- Other (please specify) – inspection that doesn't meet one of the other categories (will be used very rarely)

Q. How long will the inspection take?
A. For routine Quality System Surveillance Inspections, the FDA usually plans for one week. Starting on a Monday and finishing on Friday is a typical example. The process may take longer if they're looking for specific details regarding a Medical Device Report (e.g., the inspection is "For-cause," or if

they're exploring issues where potential violations or non-compliance is suspected.

Q. How do I know the people requesting to inspect my operation are legitimate?
A. Here's the excerpt from the IOL:
Introduce yourself by name, title and organization. Show your credentials to this person and present a properly signed, completed original of the FDA 482, Notice of Inspection

Like most business organizations, the FDA has a lot to do and organizes in a way to complete their tasks in a structured, efficient manner. There are two primary approaches to a Quality System Surveillance Inspection: Top Down and Bottom Up.

Top-Down inspections begin with your QMS, your quality manual, quality policy, etc. in this case the inspector will most likely follow the QSIT guidelines looking into the four major areas of interest along with select sub-topics as described below. The inspector will follow procedures, documentation and records down into specific products or issues.

Bottom-Up inspections start with a specific issue or product. The records and procedures related to that specific issue or product are examined in detail and the various pathways followed into higher, oversight documents.

Here's a statement about these approaches from the QSIT:
"One similarity between "top-down" and "bottom-up" inspectional approaches is record review. Both approaches involve review of raw data, or individual records.

The organization of initial, routine Quality System Surveillance Inspections follows a structure than looks at key portions of the quality system. Here's a description of that approach excerpted from the QSIT:

Rather than check every aspect of the firm's quality system, the subsystem approach focuses you on those elements that are most important in meeting the requirements of the quality system regulation and which are key quality indicators.

We have chosen four major subsystems that are the basic foundation of a firm's quality system. Those four major subsystems are

- Management Controls
- Corrective and Preventive Actions (CAPA) (with satellites Medical Device Reporting, Corrections and Removals, and Medical Device Tracking)
- Design Controls
- Production and Process Controls (P&PC) (with satellite Sterilization Process Controls)

It's important to recognize that you are responsible for ALL aspects of your quality system, its procedures and records. Even though at normal FDA

inspection may focus on only these four major areas, they're not limited to these and can ask about and review anything related to your quality system. So make sure when you conduct your internal audits, you add other subsystems as well. One approach is to perform a quarterly audit using these four subsystems as your primary topics, adding a portion (e.g., ¼) of your remaining quality system topics to each audit. In this way you will be examining and addressing issues with every part of your quality system each year.

Q. Do I have to provide the FDA inspectors everything they ask for?
A. No, not everything, as noted below in an excerpt from the QSIT, however your cooperative demeanor in working with the FDA is very important. They're just doing their jobs. You're required to comply with the law. To the extent you show cooperative, genuine interest in achieving both objectives, the relationship and the inspection activities will go much more smoothly.

When contacting the firm for the preannounced QSIT Inspection, the investigator should ask for a copy of the firm's Quality Policy and high level Quality System Procedures (including Management Review Procedures), Quality Manual, Quality Plan or equivalent documents to preview prior to the inspection. The firm is not required to supply these documents. The investigator should tell the firm that the preview of these procedural documents would facilitate the inspection. The documents would be returned at the time of the inspection. If you find deficiencies in these documents, you should request copies of the original documents after you initiate the inspection.

For each of the four major subsystems and a few satellite topics, the QSIT includes three major sections:

- Objectives
- Flow Chart
- Narrative

Below are the Objectives and Flow Charts. Prior to an inspection, or your own internal audit, you should also review the Narrative sections in the QSIT guidance document. They will provide very useful insight into the way the inspector is likely to approach the questioning.

Management Controls

Inspectional Objectives:

1. Verify that a quality policy, management review and quality audit procedures, quality plan, and quality system procedures and instructions have been defined and documented.

2. Verify that a quality policy and objectives have been implemented.

3. Review the firm's established organizational structure to confirm that it includes provisions for responsibilities, authorities and necessary resources.

4. Confirm that a management representative has been appointed. Evaluate the purview of the management representative.

5. Verify that management reviews, including a review of the suitability and effectiveness of the quality system, are being conducted.

6. Verify that quality audits, including re-audits of deficient matters, of the quality system are being conducted.
At the conclusion of the inspection....

7. Evaluate whether management with executive responsibility ensures that an adequate and effective quality system has been established and maintained.

Flow Chart:

See Figure 2. Note the references to the Quality System Regulation sections, 21 CFR part 820.xx. Most all of the Flow Chart blocks have such references, either to 820 or other sections of the regulation that apply (e.g., 803, 806, 821).

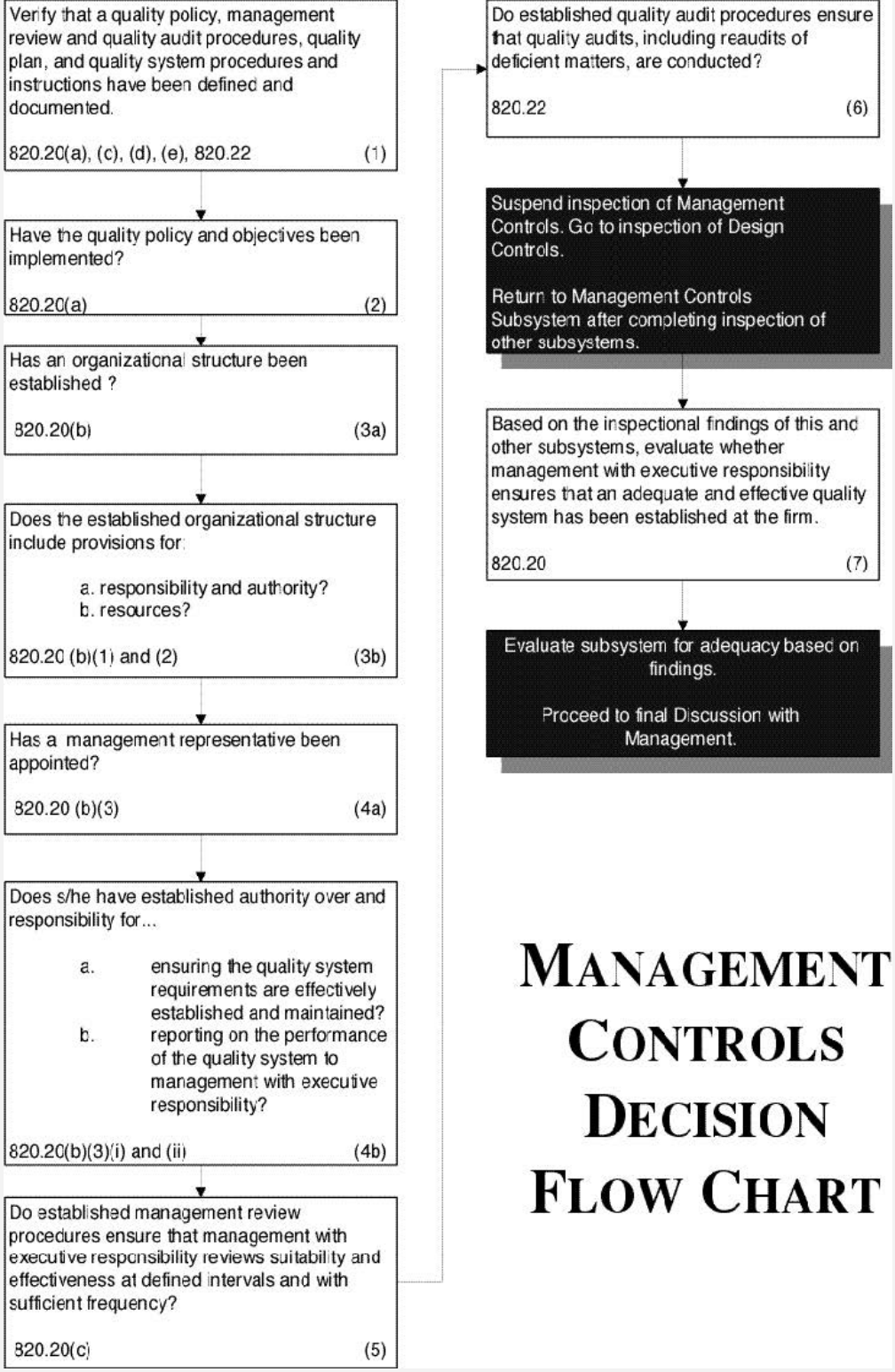


Figure 2.

Corrective and Preventive Actions (CAPA)
Inspectional Objectives

While CAPA is one of the four major areas of investigation, remember that most CAPA initiatives come from complaints. So, you can expect the inspector to review your complaint procedures and records as well.

1. Verify that CAPA system procedure(s) that address the requirements of the quality system regulation have been defined and documented.

2. Determine if appropriate sources of product and quality problems have been identified. Confirm that data from these sources are analyzed to identify existing product and quality problems that may require corrective action.

3. Determine if sources of product and quality information that may show unfavorable trends have been identified. Confirm that data from these sources are analyzed to identify potential product and quality problems that may require preventive action.

4. Challenge the quality data information system. Verify that the data received by the CAPA system are complete, accurate and timely.

5. Verify that appropriate statistical methods are employed (where necessary) to detect recurring quality problems. Determine if results of analyses are compared across different data sources to identify and develop the extent of product and quality problems.

6. Determine if failure investigation procedures are followed. Determine if the degree to which a quality problem or nonconforming product is investigated is commensurate with the significance and risk of the nonconformity. Determine if failure investigations are conducted to determine root cause (where possible). Verify that there is control for preventing distribution of nonconforming product.

7. Determine if appropriate actions have been taken for significant product and quality problems identified from data sources.

8. Determine if corrective and preventive actions were effective and verified or validated prior to implementation. Confirm that corrective and preventive actions do not adversely affect the finished device.

9. Verify that corrective and preventive actions for product and quality problems were implemented and documented.

10. Determine if information regarding nonconforming product and quality problems and corrective and preventive actions has been properly disseminated, including dissemination for management review.

Flow Chart:

See Figure 3.

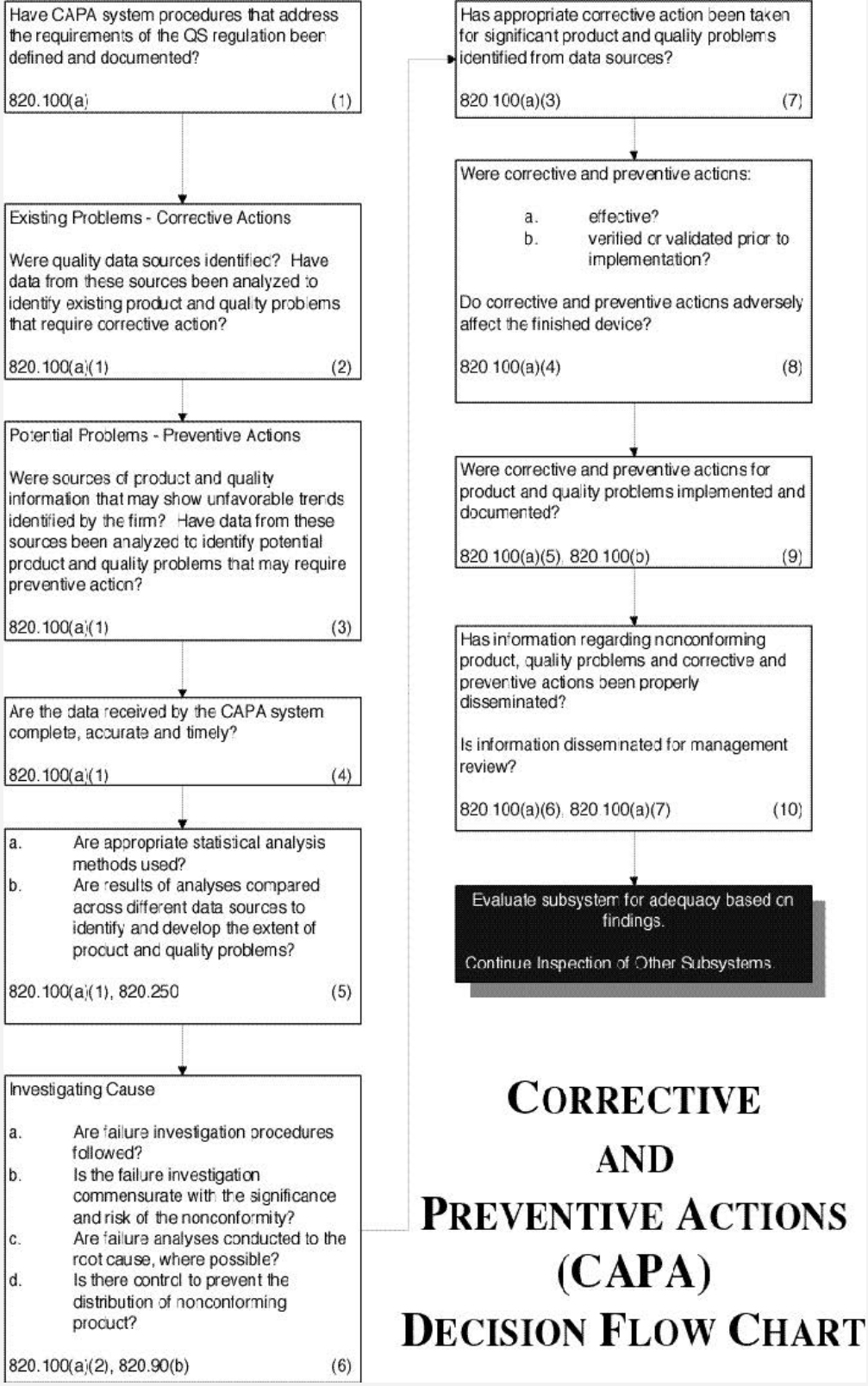


Figure 3.

Conclusion

In Part 2 we'll look at Medical Device Reporting, product Corrections and Removals, Medical Device Tracking, the very important and broadly applicable Design Controls, and Production & Process Controls including Sterilization Process Controls.

December 2021

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Boulder iQ
Innovation to Quality

Boulder Sterilization

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

Making Deciscions...

Making deciscions keeps getting more complicated and can be hard to navigate, we at Boulder iQ are here to help collect data, weigh factors, and make choices easier.

Peggy Fasano, *COO of Boulder iQ*

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Practice Areas

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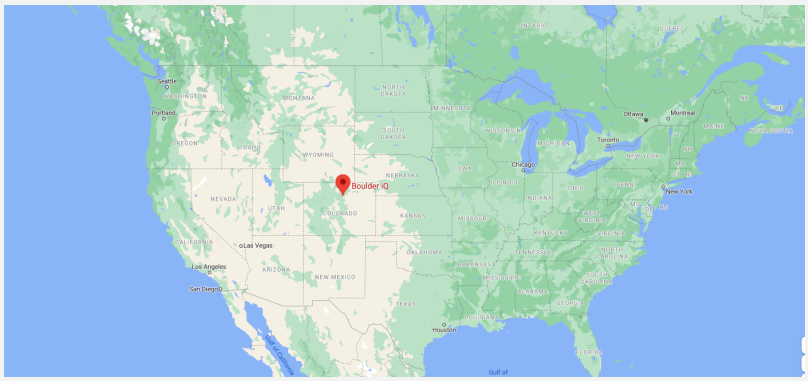

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