Boulder iQ
Innovation to Quality

Boulder Sterilization

RA/QA Engineering Manufacturing Sterilization

Be IQ: Q4 2022 Newsletter

Welcome to the Boulder iQ and Boulder Sterilization Newsletter where we provide medical device information for your company and product.

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From the Desk of Jim Kasic

December 2022…It's hard to believe it's been almost three years since the onset of the COVID-19 pandemic. To say the medical device industry – let alone the world – has gone through upheaval is an understatement. But as we close out the year and toward 2023, the industry is moving full steam ahead.

Here at Boulder iQ, we have seen a steady increase for demand in our product development and sterilization business. A few highlights:

- **Engineering, manufacturing and product development**: Business has continued to grow, with varied and challenging projects. We're now manufacturing hydrogels, and we've designed and manufactured several innovative scopes and long-term implants this past year.
- **Sterilization**: We added three sterilization chambers this year, bringing our total to five, to meet increased demands from medical device developers nationwide. We're also now providing contract sterile fill operations.
- **Process equivalency**: We began offering outsourced process equivalency service for e*thylene oxide sterilization*, addressing a critical market demand brought about by a change in servicing of sterilizers/aerators.
- **Packaging**: We've ramped up packaging and packaging validations in response to requests from most sterilization clients.
- **A growing team**: We continue to expand our team of bright, innovative professionals. Among the newest members are: Jo Rupprecht, senior vice president, regulatory and quality; Melinda Sogo, director of quality; and Mike Olichney, lead engineer. Together, they bring a combined total of almost 100 years of healthcare product development experience to Boulder iQ.

Next year, we'll be expanding our sterilization capacities further, and plan to introduce contract Medical Device Reporting for Manufacturers. We're looking forward to providing more services to more clients throughout the year. Don't hesitate to contact me if you have any questions about the development or market introduction of your device.

Jim Kasic, Chairman and Founder
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What's Wrong with the Medtech R&D Department?

By Larry Blankenship, Director
(Published as a guest article on Med Device Online)

Voicing complaints about R&D departments in medical device companies is nothing new. Executives, staff members, and investors commonly ask, "What's wrong with the R&D department? What's taking so long? It takes them forever to get anything out!" Frustrated with continual delays, and seeing that R&D often spends most of its time supporting current device product lines, it's not unusual for companies to look outside their organizations for innovative alternatives.

The reality is that R&D is indeed notoriously behind schedule and over budget, despite the introduction of countless tools and techniques to help organize and run such programs efficiently. In addition, R&D managers are serious, dedicated professionals. They certainly don't intend to be late or over budget, and they generally are conscientious in estimating the resources they believe they'll need.

So, what goes wrong? And what can be done? Here's an overview of five common culprits in delaying or derailing device development in the R&D stage — and a solution that just may be R&D's salvation.

1. (Dis)Similarity

Project management tools and approaches calculate the expected time and resources needed to implement a project, but they're only as good as the data entered into them. That data often comes from comparing the current project to previous projects that appear to be similar. The problem is that the projects may not always be as similar as one assumes, and the comparative data may or may not fit accurately.

For example, a recent catheter project was to incorporate a novel profile-changing tip. The R&D team had developed many catheters before and saw this as a "similar" project. In design, though, they found that the techniques they had used for previous catheters would not work for this tip. Instead, they needed special tooling and techniques. The result: the project went over budget by 40%. If time had been designated early on to investigate and research the needs in more depth, the R&D team could have developed a realistic assessment of what was and was not "similar" and kept the project more on time and on budget.

2. No Recognition of Research Tasks

"Engineering tasks" are those that can be successfully implemented in a straightforward, predictable manner using methods known and previously applied. "Research tasks" are those that a company does not know exactly how to do at the moment and needs to figure out. Inability to recognize the difference, and thereby not accounting for the necessity of research tasks in planning and budgeting, will severely derail R&D plans.

One real-life example of an important hidden research project comes from the intravenous pump industry. Looking at an existing a standard device that used a 5 ml reciprocating syringe, a competitor decided to leapfrog the market by making a 0.5 ml pump. Their idea was that the patient could wear the device, versus having to deal with the device clamping onto an IV pole. It may have been a great idea, but to be competitive, the developer still had to demonstrate 2% accuracy and offer similar disposable pricing. In reducing the size by a factor of 10, though, the manufacturing tolerances on the syringe could no longer be met with standard molding approaches. The resulting cost increase took the device to the point where it was no longer competitive.

3. Feature Creep

Fundamental to projecting a development timeline and budget is a solid understanding of what the product is, what it does, and how it's used. Early in the project, a product requirements document should detail all features that define these elements. Once development is underway, making any changes to that document — in effect, adding functions, or "features" — can be devastating to a planned timeline and budget.

For example, marketing may ask to add "just one more control knob on the front panel." Once the control panel has been laid out, the circuit boards printed and parts received, this seemingly simple addition can be highly disruptive to the device development.

The point at which a feature change request is made is critical to its impact. Consider a request to add an inline injection port to a tubing set. If the tubing set has already completed eight weeks of biocompatibility testing, adding the injection port may require a complete re-test, which could mean another two months — or more — to the project timeline. Obtaining enough input up front to establish solid, unchanging product requirements and avoiding feature creep later in the program is essential to project predictability.

4. Time Distractions

Protecting project resources is an important task for an engineering manager. This includes establishing policies to keep the R&D team focused on the new product's development, versus risking them being pulled away to deal with current devices issues. Importantly, it also means working with executive management to communicate the impact of such a diversion of resources.

To make this type of system work, some organizations have implemented a special engineering group, "manufacturing and sustaining engineering," to address issues with devices already in production. This allows the R&D team to focus on new devices without diversion.

5. Corporate Culture

How management deals with issues and delays in R&D sets the tone for how well the department can address issues, now and in the future. It's not uncommon for corporate executives to fire R&D managers out of frustration at delays. Those replacing them will ultimately face the same situation down the line unless the approach changes.

And, in a culture where R&D personnel fear for their jobs, they may start to inflate estimates of time and costs of project tasks to cover themselves. When such culture exists, the distrust is damaging to all parties involved.

The keys to success are to promote in-depth advanced thinking that addresses the problems described here, to work with the R&D team to plan with adequate forethought and discovery, and to execute with an eye toward predicting potential challenges and advanced preparation.

Phase 0 Solution

"Solution" may be an overused buzzword. But in this scenario, the good news is that there really is a solution to the R&D problems described. It's called Phase 0.

Simply, put, Phase 0 is a phase that comes before the typical five product development phases most medical device companies use. Those five defined phases align with the required design controls of the FDA's Quality System Regulation.

- Phase 1: User Needs
- Phase 2: Design Input
- Phase 3: Design Process
- Phase 4: Design Output
- Phase 5: Verification and Validation

Generally, each of these phases must be completed, then accepted by quality assurance, before the next phase begins, thus creating a "gate" of review and approval between each phase. While this phase-gate approach is easily auditable to show compliance with the Quality System Regulation, it is also inherently inefficient from a project flow perspective.

For example, the IFU is typically part of Phase 3 or 4, which take place when the design is largely complete. If a problem in the user interface comes up, it may require modifications to Phase 1 and Phase 2, which means going backward, not forward. Or, consider Phase 5, where verification and validation test protocols are written. The design team may not have been aware of the rigors of the testing or required test points, forcing some level of redesign.

Enter Phase 0. It involves preparatory work to determine if a device development project can even gain authorization. In fact, a main purpose of Phase 0 is to cancel development projects before they get off the ground.

Killing a project can be one of the toughest jobs for R&D managers (and company leadership). Beyond the fact that projects and devices can become so personal, no one wants to cancel a project after years of development and investment of millions of dollars. Phase 0, executed objectively, in line with sound business decisions, can eliminate emotional and subjective attachments to projects. The bottom line is that it's much easier and cheaper to cancel a project after Phase 0, before it really gets started.

A Phase 0 document clearly states that the work is preliminary investigation and research that may or may not be used as the basis for initiating a formal device development project. It therefore is not subject to FDA design controls.

Phase 0 is not trivial — or short. It typically takes several months. Yet we have seen, over and over again, for more than a decade of implementing Phase 0 with clients, that it is a wise investment. Phase 0 activities are designed to uncover the unknowns, take question marks out of equations, and eliminate the age-old adage plaguing medical device companies: "We didn't plan to fail, we failed to plan."

Phase 0 Tasks

Since Phase 0 is not subject to design controls, a company can define the activities and deliverables in a way that best serves its needs and device attributes. Many device firms work with a product development consulting firm that has hard and fast experience in the implementation of Phase 0. Whether you go this route or do it yourself, tasks usually begin with concentrated focus on defining the users, their attributes and training, and their needs in function, environment, and process. Well-organized brainstorming sessions, which include knowledgeable people outside the primary device development team, bring in objective ideas and perspectives.

From there, the R&D team can perform an initial written feasibility assessment of the top concepts, with a list of likely engineering and research tasks. Moving forward with the top two or three concepts, the team can update the device requirements document, and, for each concept, create sketches/illustrations and generate an IFU and a perceived workflow diagram.

A prime concept will emerge from user input (following ISO 62366 Usability Engineering for a Formative Usability Study). R&D can take that concept to a demonstration level, create the IFU and workflow diagram for it, and finalize based on additional user feedback.

From there, it's back to the engineering and research task list for updates and appropriate inclusion in the project plan. With the Phase 0 results, the plan — in whatever form it takes — should have buy-in from the R&D team and other corporate decision-makers. And if the project does move forward, good documentation of all Phase 0 investigations, research, tests, and activities will greatly streamline the formal design control project phases.

Identify What You Need To Know

The answer to "What's wrong with the R&D department" is a complex one, and certainly one that goes much further than R&D. Predicting, anticipating, and preparing the design, with incorporation of user needs as early as possible, can go a long way toward making R&D as productive as possible. Introduction of a Phase 0 will help identify what you don't know but need to know. In the long run, it will save the company – and the R&D department – time and money in the introduction of new devices that predictably meet customer needs.

About The Author:
Larry Blankenship is a director of Boulder iQ and has more than 30 years of experience in medical device product development, manufacturing, regulatory affairs, strategic management, and funding. He has helped multiple start-up companies in the industry get products to market, working in management positions in divisions of Eli Lilly, Pfizer, and the Battelle Memorial Institute. Blankenship is a member of the advisory board at Colorado State University's School of Biomedical Engineering and of the Constituency Committee at the University of Colorado Denver Department of Bioengineering. He serves as a healthcare industry advisor to Blackstone Entrepreneur Network of Colorado and is a former director of the Colorado BioScience Association. He can be reached at larry.blankenship@boulderiq.com or on LinkedIn.

Read Article on the Med Device Online Website

Manufacturing Strategies for Start-ups: Start Flexible

By Jim Kasic, Chairman and Founder

Your medical device may have the potential to be groundbreaking, life-saving and marketable. But it won't be any of those things unless you can manufacture it in a way that gets it to the market as quickly as possible.

For almost every start-up, time is revenue. Accordingly, the biggest challenge in manufacturing is time. Developers need to be able to make product quickly, and get it on the market as soon as possible. However, many developers lose sight of this overarching goal. The result can be disastrous.

When it comes to manufacturing, learn how to work flexibly, and how to work with a small-volume manufacturer that can help you achieve your goals in progress.

1. Look beyond unit cost. Understandably, start-up developers are usually trying to drive to the lowest-cost product in the first year of production. Low unit costs from a large-volume manufacturer can look very attractive. But that low cost can be deceiving, and come at the expense of flexibility – which can turn out to be a very real and very large expense to a start-up.

Consider that manufacturing of initial product runs quickly often requires small lots, which runs counter to the operations of large-volume manufacturers. First, they generally need to have every component and every process locked down before beginning any manufacturing. So if you are looking to make a lot of 1,000, but have a quantity of only 990 of one component, you will need to wait. When time to revenue means everything, waiting often isn't an option. Suddenly that great unit cost doesn't look so great.

Consider, too, the impact of change orders. A fact of life for start-ups, change wreaks havoc in the standardized systems of large-volume manufacturers. Implementing any change once an order is set – even if actual manufacturing has not yet begun – will take a long time and will come with substantial cost.

In contrast, a smaller-volume manufacturer used to working with start-ups will be flexible and knowledgeable about the typical issues that arise. Handling small lots will be their specialty. They'll use just-in-time (JIT) techniques, and generally charge on a time-and-materials basis, allowing the developer to get product on the market quickly. Be aware that overall pricing structure is commensurate with this approach. Don't ask for a quote to build 100,000 units and then think that the per-unit price will be a strict 1% calculation.

2. Expand your supplier profile. Often, start-ups only qualify one vendor for each part. It may be faster and seem easier, but it's far better to have several different suppliers for each component. Particularly today, as supply-chain issues continue, it pays to make the effort here. You'll gain flexibility, ease manufacturing pressures and lower stress levels.

3. Be prepared for product and process improvements. The reality with start-up devices is that early manufacturing runs will highlight problems and pinpoint needed iterations. Train your mind to stay flexible and prepare to move fast with these changes. Do your homework to find a manufacturer that will be open to changes, and that can keep up with them.

4. Stay close to home. Manufacturing locally – when possible – provides the greatest degree of flexibility. On the other end of the spectrum will usually be the overseas large-volume manufacturer. While pricing makes it tempting, be aware of potential issues that could impact your time to market – and revenue. Frequently, there can be issues in obtaining the documentation packets needed for medical devices. In other cases, it can be difficult to transfer manufacturing out of another country down the road. It pays to think ahead.

As an example, here at Boulder iQ, we had a device start-up client that received its CE mark to sell in Europe. Because the company's cost of goods did not provide a strong enough margin for long-term success, they shut down manufacturing with us and took it overseas. As a result of complications of working with the large-scale manufacturer and its strict processes, they were unable to get manufacturing off the ground. The company ran out of money and was forced to close before it could sell a single unit.

5. Have short-term, medium-term and long-term plans. For maximum flexibility, avoid getting stuck on generating a high margin early on.

- Short-term (now): Yes, margins are important, but as a start-up, your top priority is to get product out there on the market and obtain customer feedback.
- Medium-term (12-18 months): Focus on modifying and finalizing your device based on that feedback and early results.
- Long-term (2 or more years): Move to high-volume manufacturing and making a good profit.

Walk before you run

Start-ups can become so worried about making a high margin early on that they never complete the journey. That means never generating real revenue and never getting to the point of becoming a serious funding or acquisition target. If you're seeking funding, remember that potential investors love to hear that the market loves your product, and what you need is capital to drive cost down. If you're fortunate enough to have an acquisition, the acquiring company will be able to work with you to drive the cost.

Take it one step at a time, and make sure you take those first manufacturing steps carefully. Unless you're incredibly well-funded and are absolutely positive your product won't experience any changes, crawl before you walk, and walk before you run.

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Team Member Spotlight:
Mike Olichney

Boulder iQ's new lead engineer is a man of principles.

"I'm a first principles guy," says Mike of his approach to engineering. Referring to the reasoned thinking that requires breaking down a problem into its fundamentals, he operates on the basis that things should work on paper first, before building prototypes and conducting testing.

A manager with a strong analytical background, Mike sees his approach as complementary to Boulder iQ's. He likes the number, type and variety of projects the company has going at any one time. "It's interesting because you see a lot of different technologies," he explains. "And it offers a good challenge because you have a lot of people to deal with and things to keep track of."

Mike comes to Boulder iQ with more than 35 years of medical device engineering experience, primarily in new-product development. His expertise includes mechanical and disposables design, materials selection, fluids modeling, sensitivity analysis and statistical methods. He is proficient in designing test, and verification and validation, programs, and is well-versed in FDA regulatory issues and programs. Serving as inventor on more than 15 U.S. patents, he holds a Bachelor of Science in Mechanical Engineering degree from Rice University.

Joining Boulder iQ presented a good opportunity to combine several of his interests and talents: managing, engineering and mentoring. Mike comments that one of the most favorite and rewarding aspects of his work is mentoring young engineers. Working with young adults right out of school, he is able to provide needed direction and opportunities while setting a good example. "It's important not to micromanage," he says. "Instead, you learn to give just enough direction for new engineers to make progress and the right decisions."

Mike lives in Castle Rock, Colorado, and during his commute to and from the Boulder iQ office, he continues to focus on maximizing productivity – often on business calls, catching up on details of projects with the other engineers on his team.

When he's not working, he enjoys spending time on his mountain bike and with his family. Married since 1995, Mike and his wife have two children. Their son, a graduate of the University of Colorado, is a computer programmer. Their daughter will graduate this year from Northern Arizona University with a degree in environmental science.

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Boulder iQ is an expert contract consulting firm providing all the services life sciences companies need to get their products to market as quickly and efficiently as possible. We serve as a single source for device developers, providing full product development and regulatory services under one roof.

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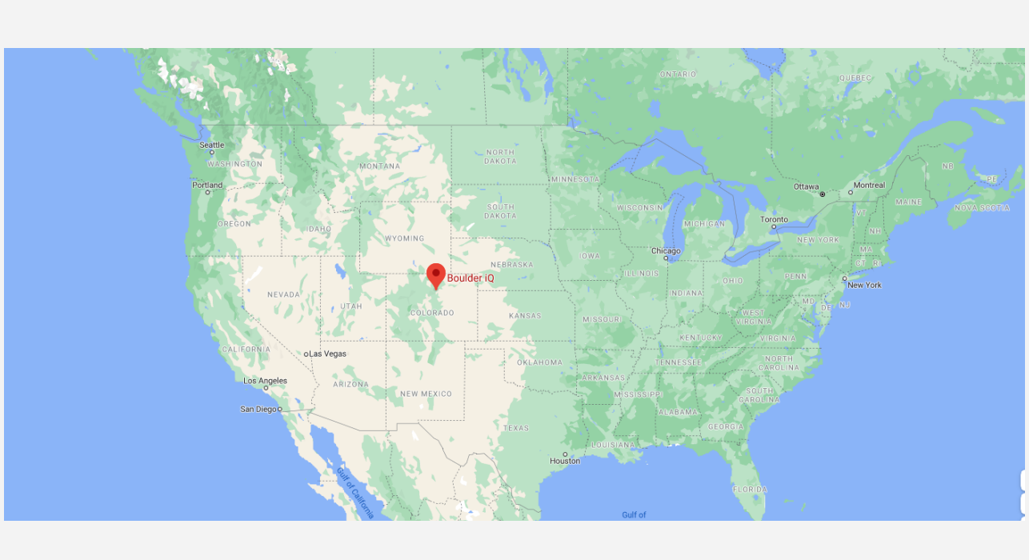

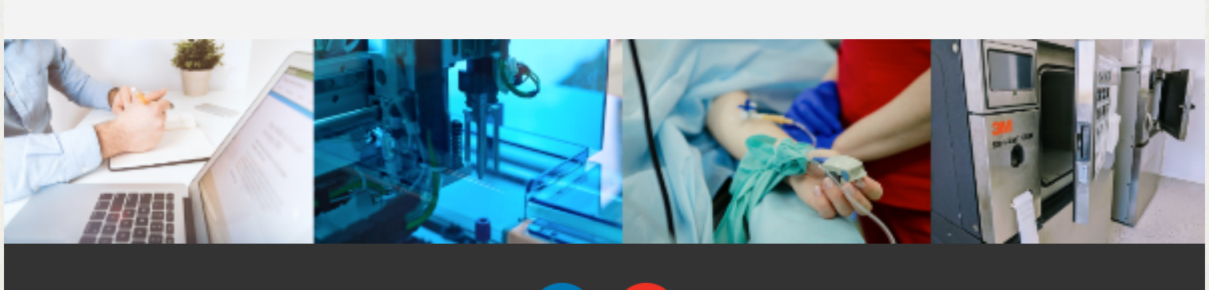

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