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■ ON THE COVER

There are no shortages of innovative ideas that advance medical technology. The challenge is how to bring great ideas to market within today's regulatory environment and reimbursement structure and within a reasonable timeline and budget. With the added challenges of dealing with the uncertainties and shelter-in-place requirements in response to COVID-19, it is especially difficult to keep up with the schedules, budgets, and project goals. To learn three keys to success that separate those organizations that consistently deliver innovation, read the article on page 10.

(Credit: Canon Medical Systems, Video Sensing Division)

MEDICAL DEVICE Innovation:

Three Keys to Success in the Face of COVID-19

There are no shortages of innovative ideas that advance medical technology. The challenge is how to bring great ideas to market within today's regulatory environment, reimbursement structure, and within a reasonable timeline and budget. With the added challenges of dealing with the uncertainties and shelter-in-place requirements in response to COVID-19, it is especially difficult to keep up with the schedules, budgets, and project goals. What separates those organizations that consistently deliver innovation, maintain competitive advantages, and achieve commercial success?

What are the keys to success that drive innovation? Three elements are critical to supporting innovation and market leadership: 1) a strong business plan, 2) good communications, and 3) utilizing outside resources. When implemented, these three elements transcend markets, products, technology, and business structure and can be used within any business or start-up to provide a resilient foundation for successful medical device innovation.

While COVID-19 adds to the complexity and challenges of medical device innovation, it doesn't change the process. Rather, it simply adds another dynamic that must be considered. Medical device development and innovation is increasingly complicated and highly regulated, and it involves every functional aspect of the organization from quality, manufacturing, supply chain, marketing, and sales, to regulatory and clinical efficacy. The enormous development costs, financial risks of missing the mark, and critical market timing all contribute to the extreme challenges of medical device development and market driving innovation.

Having a strong business plan, implementing good communications, and utilizing outside resources can provide a resilient foundation for successful medical device innovation. (Credit: Canon Medical Systems)
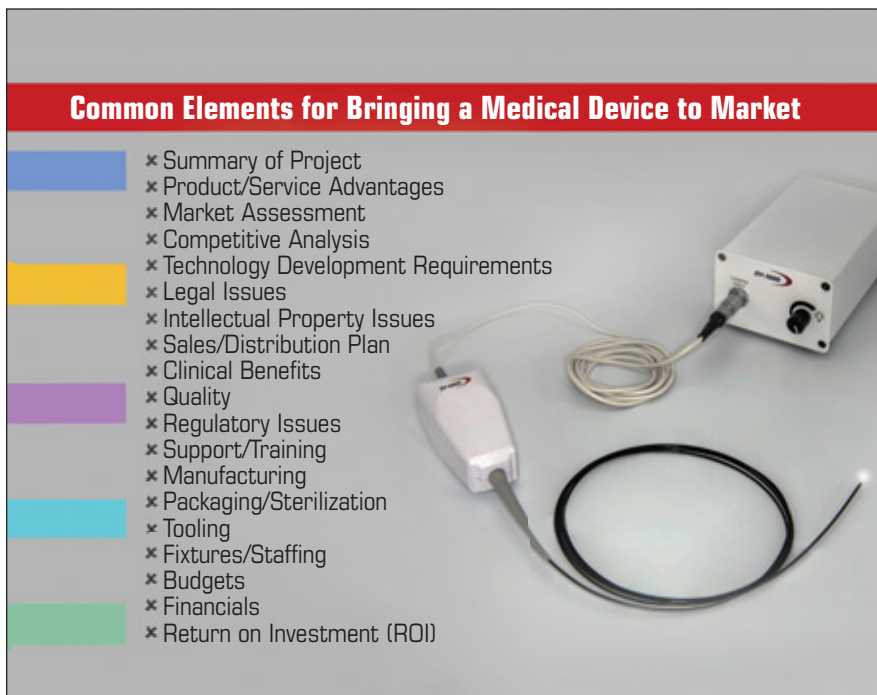
Common Elements for Bringing a Medical Device to Market

- Summary of Project
- Product/Service Advantages
- Market Assessment
- Competitive Analysis
- Technology Development Requirements
- Legal Issues
- Intellectual Property Issues
- Sales/Distribution Plan
- Clinical Benefits
- Quality
- Regulatory Issues
- Support/Training
- Manufacturing
- Packaging/Sterilization
- Tooling
- Fixtures/Staffing
- Budgets
- Financials
- Return on Investment (ROI)

Fig. 1 – Common elements for bringing a medical device to market.

Key 1 – A Strong Business Plan

The importance and value of preparing a strong and cohesive business plan cannot be overstated. One wouldn't begin to build a house without first having a detailed set of plans including structural, mechanical, electrical, plumbing, seismic analysis, bill of materials, and budget. In a similar way, one should not consider development of a medical device or introduce a health tech service without first preparing a comprehensive business plan.

Spending additional time at the front end, before development starts, to prepare a detailed business plan will save time and money in the long run. In addition, the process of preparing the plan will ensure that all aspects of the project have been considered. It will aid in building consensus and educating stakeholders, and it will serve as the backbone for the project. Having a well-constructed business plan will help when unexpected interruptions, such as COVID-19 events, come into play, as the impact of these disruptions can be easily applied against the business plan to identify areas of risk to the schedule, market, and budget.

Many companies have an existing business planning template to follow. If a company doesn't already have a system in place, the Small Business Administration (SBA) provides some excellent resources and guidelines on what elements to consider when preparing a business plan.[1] A number of software tools can be found to facilitate preparation of a business plan and there are independent consulting firms that can assist in key areas or preparation of the entire report.

Business plans often follow one of two formats: traditional or lean start-up. Briefly, a traditional business plan will include all aspects, from start to finish, required to support the definition, project scope, and requirements to conceptualize, develop, commercialize, and support a product or service, In contrast, a lean start-up business plan may prioritize and focus on a few key essentials such as market identification, technical requirements, and financials, allowing other elements to be developed over time. If the business is a start-up or seeking outside investment, it may be beneficial to hire an independent consulting firm that specializes in preparing business plans and investor presentations and is experienced in medical markets.

Best practices and companies that consistently deliver on introducing great technology to fulfill a market need, invest significantly on the front end to develop a strong business plan, which serves as a tool for communication, establishing key milestones and accountability. This front-end activity can consume a lot of time, but it also protects the investment and minimizes the risk of committing significant staff and financial resources only to see a failure during commercialization. One common shortcoming is that the business plan focuses on the technology development and fails to adequately define the market, sales, distribution, and competitive landscape. These fall into the "if you build a better mousetrap, the world will beat a path to your door" category.

Without considering the sales and distribution, even the greatest technology can fail. Or a compelling technology, combined with a well-defined sales plan, can fail due to a lack of understanding of the competitors' strengths, market acceptance, reimbursement rates, and existing alternatives that may be available in the market. Taking the time to fully prepare a solid business plan ensures the best chance for success (see Figure 1).

Key 2 – Good Communications

Having an excellent business plan as a guide serves as the foundation for medical device innovation but the plan by itself is static and lifeless. It is through communication that the plan takes life and supports administration, identification of key milestones, accountability, and course corrections when needed. Communication guides the specific activities against the plan and provides crucial visibility to keep stakeholders engaged and minimize missteps along the way.

The recent impact that COVID-19 has had on the economy and most businesses has revealed the importance of communication and the need to consider alternative methods of keeping your team informed and up to date. Thankfully, there are great communications and collaboration tools to help many people successfully work remotely and support the business, despite not having physical offices to work from. During the peak of work restrictions in the initial stages of COVID-19, at Canon Medical, for example, the development staff were working in alternating shifts and days in a three-group rotation. Due to the protection of proprietary information, there are limitations on the work activities that may be performed remotely. As a result, there had been a reduction in productivity and necessitated effective communication practices to ensure that all development teams were working together.

What information needs to be communicated and what is the best method and frequency of updates? These will vary by project and company. Direct development teams or task-specific work groups should update within their team regularly; usually weekly or bi-monthly is sufficient. Be sure to assign someone the task of maintaining and distributing meeting notes, ensuring that the data is being captured and updated appropriately. Use of collaboration tools to which everyone has access is a great way to track progress, document milestones, and highlight areas of potential risks. Many use a green, yellow, red status flag system to visually identify components that remain on track vs. ones that are facing challenges or may be at risk.

Broader, cross-functional team meetings can be held regularly but with less frequency than specific work groups. Set discussion objectives and publish agendas for these meetings in advance to keep them on point with clearly identified action items. Assign time limits for each work group report, 3–5 minutes. If additional time is needed for discussion, that should be determined in advance and added to the agenda. If there are special topic concerns, such as how COVID-19 may be impacting schedules, deliverables, or budgets, make sure these are identified as specific topics for reporting by each work group. If a more open-format, roundtable discussion is needed, suggest pulling that off-line to get resolution prior to presenting it to the group, rather than bringing it into a regularly scheduled meeting. This technique can also be used if during a meeting discussion gets caught up into too many details that are not relevant to the group as a whole. If it begins to drift off topic, invite those affected to discuss off-line and update their conclusions and resolution at the next meeting. One option is to implement a "pick-up the phone" rule if an e-mail chain gets bogged down by more than three iterations to reach a conclusion or confirm an action plan. Texts and e-mails can be great tools but sometimes issues can be resolved more quickly with a phone call.

When should one share bad news? Do you share everything as it comes — good, bad, or otherwise — or do you hold off and hope the situation may improve before getting everyone worked up over an issue that may or may not occur? The short answer is, it depends on the organization and specific details

Fig. 2 – Keys to success include having a strong business plan, good communications, and leveraging outside resources.

of the situation. Generally, if the information involves an impact to schedule or budget, or if it requires a decision for compromise on a critical technical or operational path, these should be disclosed to the team as early as possible. Once confirmed, don't hold onto information any longer than necessary. Sometimes it's best to rip off the Band-Aid. It will hurt a lot at first, but then everyone can work with it and consider available options and countermeasures.

Canon Medical, for example, had a recent situation where a critical tier-three supplier had been completely destroyed by a natural disaster. Since it was a tier-three supplier, the impact was not immediately apparent and by the time the real situation had been disclosed, several weeks had passed, creating a severe impact to production and customer deliveries. Once the company confirmed the severity of the situation and had a rough idea of the scope of the impact, all affected customers were contacted to inform them of the issue, discuss any corrective action options, and schedule regular update meetings to closely monitor the progress. While alternate vendor options were possible, the development and qualification of a

new vendor did not provide any schedule improvement. However, they would provide a contingency in case of a similar disruption to this component in the future. Keeping everyone updated on a regular basis didn't change the outcomes, but it did build confidence that every effort was being made to improve the schedule as quickly as possible.

Key 3 – Use of Outside Resources

Very few organizations have all of the know-how, resources, and capabilities under its own roof to successfully bring a project to market. Successful organizations recognize how to balance their internal capabilities and resources with those outside of the organization to leverage the best of both to improve costs, shorten development time, manage risks, and potentially strengthen the technological advantages of the product or service.

With a strong business plan and good communication, it should become clear which aspects for the project fit best within the core competencies of the organization. Project requirements that cannot be easily achieved within the organization need to be addressed by staffing up and bringing resources in-house, or seeking outside resources that

may be available to fill the gaps. Which elements of a project make most sense to go outside will vary by project and for each company. It could be specific design and/or aspects of the technology; it could be quality, packaging and sterilization, manufacturing, or distribution. The first outsourced component might be the preparation of the business plan, as mentioned earlier.

For example, one company had a capable engineering staff, competencies in all of the technology areas and the means to manufacture, support, and distribute the new product. Despite these capabilities, they elected to outsource the full project including development, manufacturing, and packaging. Their supplier had a capable engineering staff, technological competencies, and the capability to manufacture, support, and distribute the new item. Their reasoning to use an outside resource was based on the fact that the product was needed for an emerging market application for them, and it would have been a development distraction with an uncertain ROI. In this instance, the value of outsourcing was convenience, time to market, and offsetting an internal risk to an outside resource. The project was not without its issues, but in the end, both organizations benefited by leveraging their respective expertise and strengths. This is the ideal situation for use of outside resources.

Summary

Any individual, development team, or organization can successfully bring an idea from concept through commercial launch by applying these principles. The tools available today can be used by organizations of all sizes and capabilities to facilitate the development of a business plan, support dynamic interdepartmental communications, and utilize external resources. By managing and intentionally applying these keys to success, any organization can achieve its goals and deliver market-winning innovation to the medical industry (see Figure 2).

Reference
1. "Write your business plan," U.S. Small Business Administration, https:// www. sba.gov/business-guide/plan-your-business/write-your-business-plan.

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