



YOUR MEDICAL DEVICE BUSINESS

A Technology
Roadmap to
Success

By Scott Frappier

Solutions Architect at Stoneridge Software

**Stoneridge**
software

Your Medical Device Business – A Technology Roadmap to Success

Let's get the bad news right out in the open: Most medical device startups fail*. Setting up your medical device company for success takes realistic planning and investment at the outset. Like anything else done well, you can invest the time and money now, or you can do it later. Whichever approach you take, a strong foundation built with powerful business tools will help your business thrive. Regardless of your vision for the future – whether it's to build a company for the long term or build a device to be sold to a major device manufacturer – your company's success boils down to meticulous planning and building a solid business framework for your concept from the very beginning.

Build Your Dream on a Foundation

Every medical device company idea starts with a dream, exciting visions for improving people's health and building a successful company. If you're reading this paper, you likely have that big dream as well as a practical head for business. Understanding and embracing that your organization must consider decidedly unexciting things like budget management and project tracking is how you can turn your concept into the profitable success you and your partners dream about.

"By failing to prepare, you are preparing to fail."

-Benjamin Franklin

Decisions your organization makes at the beginning will have major ripple effects on the outcome down the road. The quality of these decisions could impact whether or not you are successful. By integrating powerful business tools into the fabric of your medical device startup, you can build a foundation that positions your company for the outcome you envision.

Pre-Market Phase|Concept

In the medical device universe, the pre-market phase is where the foundation is built – for the device and for the business. The majority of the work happens here, as the design is developed and built in this phase. And while the ingenious invention is for you and your team to build, it's a very good idea to also have a team working on implementing reliable business tools and risk management strategies as early in the process as possible.



Day One: Wrangle the Budget

Regardless of where you acquired your funding, you will need to have a close eye on accounts payable, general ledger, cash management, banking, costs, and have predictable financial reporting tools in place from day one. It won't be a surprise to hear that many of those medical device startup failures are because they didn't watch the budget and ran out of money before they could get to production. Close management and clear line of sight on the budget is essential to your long-term viability.

In addition to keeping track of money and budgeting wisely, you must have the ability to point back reliably to your financials if your goal is to be positioned for acquisition after launch. If you can't clearly demonstrate the financial history of the invention, you may be seen as too much trouble for companies interested in your device. And if your plan is to build a long-term business from this device, access to historical and current budget

Recommended Technology

Microsoft Dynamics 365

This where you track your budget, project management and general ledger information.

Office 365

Take data out of your system and report quickly and easily with this familiar applications

Microsoft Power BI

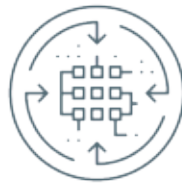
A powerful tool that helps you visualize and react to data that exists within your Dynamics 365 and other systems.

Devices – tablet, phone, PC

No longer are you limited by the type of device that you interact with. The data is visible and you can interact with it from any device at your disposal.

analysis will accelerate any loans or funding opportunities you decide to pursue.

In this phase we recommend that you implement a customized dashboard to track budgeting and forecasting, build a view into forecasts for upcoming expenditures, and access insights into any trends aligned with your finances and activities. With this integrated budget and project management system, you and your team will know at all times where the money is, how cash flow is holding up, where it's being spent, and whether you have enough money to make it through to FDA approval and beyond. At a glance, you, your investors, and other stakeholders need to have instantaneous line of sight into the financial health and overall viability of the business.



Start Tracking the Project...NOW

Arming your startup with a reliable, accessible, project tracking mechanism, implemented early on, positions your company for success down the road. While it could be years before you head into the market launch phase, you will be glad you tracked every element of the project from the beginning.

What do you need to track? Everything. Literally, EVERY SINGLE COST and ACTION related to the development of the device. R+D, payroll for your staff and vendors, formulations, equipment/capital assets, patents, soft costs, trials, potential customers, potential investors. The ability to point back to each dime spent and every activity in the life cycle of development not only can lead to recoupment of initial costs, but also could be the difference between getting acquired by another company or being passed over.

For something that sounds so simple, costs can be one of the more complex elements that needs to be clearly tracked throughout the entire life cycle of your device development. What are the true costs of developing this product? People. Research. Design. Materials. Regulatory diligence

and compliance. Manufacturing. Marketing. That's a partial list. Have you thought of all the costs? Have you correctly projected those costs? If you're worried you forgot something, you may very well be right.



Build a Dashboard

Your business's customized dashboard, reliably tracking exactly where you are in the development cycle of the device at any moment, will help you build a success roadmap for this device and anything that comes after you've gone to market. Examples of what you can easily access include in your dashboard includes; what capital assets have been purchased, what needs to be purchased down the road, costs associated with clinical trials, clinical trial modalities and outcomes. This reliable business infrastructure system will factor in all of the dimensions of your project and easily produce reporting, so everyone involved can see the plan and the future. And a well-designed dashboard will be flexible, so that as your business grows and becomes more complex, the dashboard can keep up with it.

Reasons Why Power Bi

Ease of use

A familiar interface to easily create charts and graphs that look at the data within Dynamics 365. It's simple to set up and anyone can use it.

Accessibility

It doesn't matter where you are or what system you're in. If it's on the Microsoft platform you can access it from anywhere, at anytime on any device.

Interaction

Allows you to quickly and easily create charts that link to each other. There are real-time interactions with data including visualizations, as opposed to running a static report.

Artificial Intelligence (AI)

The future is here. If the data exists in the system, the intelligence is there to create interactive visualizations simply by asking the question and saving new views to your dashboard.

Build a Marketable Device



Clinical Trial/Certification

At risk of stating a painfully obvious fact, the clinical trial phase of medical device development is intensely complex, even for relatively simple devices. The focus here from a business infrastructure standpoint, regardless of how long clinical trials take and how complex they become, is to properly plan, execute, document, analyze, and evaluate all aspects of the device at every stage of the trial.

Having a market-approved and certified device means it strictly complies with regulations and requirements and is ready to go to manufacturing and market. Does your business infrastructure track and prove the certification? Bottom line, it's a non-starter if it doesn't. Building a centralized application management system into every aspect of this device's development, especially the certification stage, is critical path to your success.



Production/Manufacturing

You've made it through the regulatory gauntlet and are now officially manufacturing your device. Congratulations! In this point of the journey, customizing your business dashboard to track inventory, serial numbers, raw material requirements, ordering, vendors, stock levels, early demand forecasting, assets, depreciation, components, quality and inspections results, and manufacturing detail is essential to keep the business on track and right-side up. If any material

changes are made to the device, re-trial and re-certification cycles need to be factored in and quickly documented in your internal processes.

Without integrated business processes, attempting to use disconnected tracking and financial tools isn't just a nightmare, it's dangerous to the viability of your business, and possibly a liability. Building the fully integrated business infrastructure at the outset will make these later phases more accurate and simpler as your business matures.



Keep on Tracking

Once you've produced and launched the device into the market, it doesn't mean you can let off the gas on tracking all of the elements of your project. The need for financial vigilance, deep insights, and documentation for your device will continue to be of paramount importance until you are acquired or settle in for the long haul as a business.

Heading into market launch mode, you will need to add need line of sight into current analytics, inventory management, and warehousing. The ability to demonstrate the history and progression of the device from inception to current day will be required, frequently. Regulatory scrutiny on medical devices means you must show clinical data on newly invented medical devices, and that means you need to collect ongoing data from inception to maintain certification through launch and beyond.

Recommended Features

Microsoft Dynamics 365

MRP/MPS

Aligning what you need to purchase and produce based on market demand

Traceability

Being able to understand what materials went into the building of a product. In case of a recall you would know the impact within the supply chain.

Quality Management

Ensuring the correct test cases and measures are adequately being defined and enforced to ensure proper quality standards of your product.

Manufacturing Execution (MES)

Makes it easy for you to understand at each step what needs to be done as part of the production of each device.

With the right tracking and historical information at your fingertips, your business can weather any and all diligence inquiries. And your team's access to demonstrated, documented quality control and proof of compliance with regulatory requirements will save time and potentially be the second most valuable asset you have to offer, after the device itself.



Market Launch

Inventory/Shipping/Forecasting/Purchasing

Can you easily track exact inventory locations at any given moment? Your ability to immediately locate inventory and keep the right amount of stock on hand for demand will make your day to day processes more efficient and can set you apart from other medical device manufacturers who aren't as organized and automated. Do you know what materials you need to order to keep up with demand? Are you on top of the orders that are coming in, with item tracking and tracking and shipping dialed in? Believe it or not, there are ways to predict inventory and forecasting demand for your device.

At some point along the product development continuum, demand forecasting will become a necessary function in your business processes. The ability to identify, monthly or even daily, how much to produce and how much has sold will help your team project demand. Your business tools should consider yield vs scrap in the manufacturing process, keeping waste to a minimum and profits maximized.

If you are paying your vendors on time and tracking those payments in your integrated operational processes, then you are miles ahead of your competition. Likewise, if your shipping and receiving insights are readily available to the team that needs them, then you're part of the digital transformation that has already disrupted the medical device market!

The simple truth is that the best medical device ever built will stay on the shelf without tools to ensure the device can be sold at a profit. And, if your invention is good, there are tools to ensure your business can succeed.

Marketing and Sales

You're almost there. You're almost to the end of the hardest part of your journey. At this point, you've dialed in all of the issues around ordering, shipping, forecasting. Now, it's up to your sales and marketing teams to get those devices out the door and into the hands of the customers. Now is definitely NOT the time to disconnect your processes. Integrated sales and marketing tools will help you turn prospects into happy customers and allow your teams to have just-in-time information to impress and delight your prospects. With the right tools, you can move far beyond basic email campaigns to integrated, exciting, automated campaigns, respond to changing circumstances quickly, and set yourself apart from your competition with innovative ways to get your message out and interact with your customers.

Recommended Technology

Microsoft Dynamics 365 for Sales

For tracking your sales performance and analyzing your interactions with prospects and customers.

Microsoft Dynamics 365 Marketing

For the creation and nurturing of prospects into sales opportunities and then clients.

Microsoft Dynamics 365 Business Central

A platform for all the operational aspects of your business, from cash to budgeting and AP/AR to financial reporting and manufacturing for your SMB business.

Dynamics 365 for Finance and Operations

Platform for all the operational aspects of your business, from cash to budgeting and AP/AR to financial reporting and manufacturing for Enterprise businesses.

Post Market Success

Acquisition or Next Gen Company?

Most Medical Device startups have their eye on a certain prize. Around seventy-five percent of successful medical device manufacturers eventually position themselves to get acquired. If that's your goal, in acquisition you will be asked to provide reporting on all the details that went into the development of the device, from day one. Integrated business processes that show the entire continuum of the device lifecycle can remove guesswork out of acquisition diligence processes. The more detail you can show, the more valuable your business may be to the acquiring company.

Examples include year over year growth, seven-year history, defect rate, common defects, patents, ROI and virtually every other trackable element for the business.

Even if you have decided that you want to keep the company and build on the original device, these connected systems will continue to sustain your business and help you continue to innovate and scale as you grow.



The High Cost of Cheap Information Silos

There is a temptation with many startups to try to sidestep investment in some aspects of the business tools, usually borne from a misplaced goal of “saving money”. In fact, one recent study showed that only 40% of medical device manufacturers use integrated, specialized tools during the development and launch lifecycle of their devices**. What this means to you is that, with the right innovations in your business processes, you can be light years ahead of at least 60% of the overall medical device market. In your niche chances are that your competition isn’t investing here, which is an automatic advantage to you.

One common example of where companies sidestep investment is tracking for their clinical trials. While we recommend integrated, connected processes across all aspects of your business, the clinical trial phase is most definitely not where you should drop the ball. Every detail of your clinical trials needs to be documented, from the location of the trial to all of the intricate details, as well as outcomes and follow ups. Startups that resort to messy, confusing tracking spreadsheets in this phase can cause themselves major headaches with regulators and future business partners down the road. Your ability to hand off clear, concise, easily consumed reporting on all aspects of the device development, from day one, will help clear the pathway with interested parties.

With the right business operations solution in place, every key element of your business is integrated. Everyone on the team is armed with the insights necessary to make critical business decisions. With systems that are connected, every aspect of your production, sales, marketing, and operations are fully optimized and controlled.

Worried you're figuring this out too late?

It's ok if you started down the path on developing your device, piecemealing disconnected business tools together. You aren't the first company to do things that way. Even if you've already developed the device and are into its production, you can retroactively build a foundation that will position your company for acquisition or long-term growth. Like anything, getting caught up may take some time and investment, but implementing the right business tools for your future success is always a good idea.



A Solution for the Entire Roadmap

(+ Choose the Right Partner)

Regardless of the steps you take to build a medical device, you know by now that you need a predictable, robust business infrastructure as early as possible to be successful with your medical device business. The technology mapped out in this white paper is best in class and will help to provide a necessary framework for the business side of your invention. Every step, every process, every stage of your device requires unique solutions. One of the most essential decisions in your business is which partner to choose to bring your integrated business tools to life.

When deciding on a partner, consider the following questions:

Do they already have experience working with Medical Device companies?

Are they top-tier experts in the technology that's needed for your business infrastructure?

Do they have a track record of successful projects?



At Stoneridge Software we've developed a proven process to guide clients along the journey to success. And we're with you every step of the way.

Setting up an integrated business infrastructure isn't the easiest thing you'll do. It takes the right partner, concerted effort, and a dedicated, talented team to get it right. But the peace of mind that comes with having all of your business insights, actions, and financials in order from day one can ultimately mean the difference between achieving your wildest dreams or having your business fail before it even had a chance to succeed.

Learn more about how Microsoft Dynamics puts your medical device manufacturing firm on the road to success. Contact Stoneridge Software.

