

Medical Technology Commercialization: Making it Happen

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If you are a medtech investor or a medtech company executive responsible for making investment decisions, you want to place your bet on the commercialization opportunities that have the highest probability of success, lowest investment cost, shortest time to market and the greatest return. Successful commercialization of medical technology has several keys; clear objectives and goals, great leadership, a robust commercialization process, solid planning, the right resources, and relentless execution.

In the July LifeScience Alley Newsletter we talked about

why commercialization processes are important to the success of new medtech businesses. In this article we will take the discussion a step further and talk about some examples of how using or not using a commercialization process can contribute to medtech business success or failure.

Robust commercialization processes:

Project management and planning are key elements in the successful execution of medical product commercialization. Project planning helps program leadership chart the course from one milestone to the next, iden-

tify and quantify key resources needed, as well as the timing and interactions of various efforts. It also identifies the critical path and how to shorten the time to market and ultimately helps to optimize the resource investment.

Another key component of commercialization processes is planning checklists that identify important tasks to be completed by certain timeframes and typically identify which function is responsible. Results relative to these checklists are typically reviewed at phase gate meetings. As an example, one unique and critical

issue for medical technology products is the issue of Medicare and/or insurance reimbursement. Patients are frequently unable or unwilling to pay the costs of medical products and/or procedures that can run into thousands and tens of thousands of dollars if they do not have help from their private insurance or Medicare. Early in the commercialization process, typically in the Concept Development phase, it is important with medtech products to identify the reimbursement status of the new product, develop a plan to obtain reimburse-

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ment approval if needed, and identify the tasks and risks involved. Lack of Medicare reimbursement can be a major problem for a new medtech business in driving market acceptance and adoption. This single issue has been the cause of many medtech business failures. A good commercialization process helps businesses avoid underestimating this and other critical areas.

A robust process also helps leaders manage the complexity of new medical technology product commercialization with greater efficiency and reduced risks. For example in the case of a new product that requires a significant amount of technology development a frequent challenge is making sure the technology development is truly complete before moving into later phases. Incomplete technology development can force product redesigns that can cause a cascade of changes that may force an entire program to take a step backward resulting in delay, higher costs, and even failure. FDA regulations make this issue more problematic than in other industries because some critical testing is considered invalid if it was done using a design that has changed. Identifying and planning for ahead of time, the criteria that must be met

in order to avoid this kind of problem, is critical.

Use of a good commercialization process helps the individual commercialization team members understand their role in the success of the program and how their role fits in the bigger picture. So many aspects of medical technology commercialization are interrelated with one action depending on and also impacting many others. For example, completion of the regulatory plan may be needed before R&D or Quality can estimate the time and resources needed for completing pre-clinical testing. The regulatory requirements and clinical testing plans can depend on the marketing claims designed to communicate the unique value to the customer. These claims also influence and depend on the capabilities of the technology being implemented in the new product. As this example illustrates, coordination of various discipline's efforts is essential to commercialization success.

The value of gate reviews:

Gate reviews not only provide management or investor approval for moving forward with a project, they are an important vehicle for communication. They give the commercialization team the opportunity to communicate program status, critical is-

ssues, and to take a proactive approach for communicating plans to address the issues with senior management or investors. They are also a venue for keeping both the commercialization team and management on the same page and focusing on the priorities and key milestones to be accomplished in the next phase. Senior management or investors will have higher confidence in their commercialization teams if they believe they are being kept well informed of the issues and risks as well as the progress.

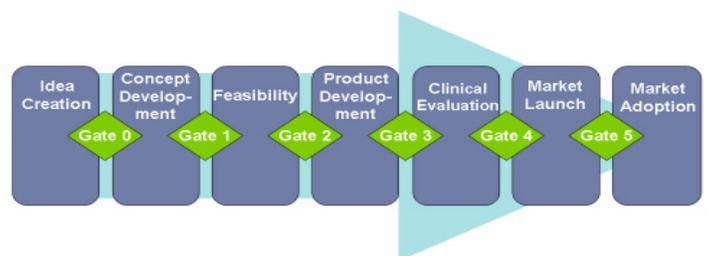
Implementing the commercialization process:

Creating a solid commercialization process is best done with experience, utilizing the knowledge of professionals that have been there before and can see the big picture across the many functional areas involved. It also requires collaboration between the various functional groups that play a role in the

process. While every product commercialization effort has unique issues and conditions that need to be taken into account, a well designed process can be used as a template which is modified to fit the specific product or program. Once developed, it is important that the organization is educated in the process, its importance to the success of the business, and their role in the process.

In summary, most successful medical technology businesses begin new product commercialization efforts with a clear end in mind and a well thought out plan for how to get there. A robust commercialization process and solid planning help these companies handle the challenges that arise during the commercialization process with significantly less negative impact on time to market, investment costs, and ultimately, commercial success.

Phase / Gate Commercialization Process:



Waterford Consulting, Inc. / MedTech Leadership, Inc.