



## Medical Technology Commercialization: Getting Great Ideas to Market

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The essence of success is in the results. Many brilliant people have great ideas; unfortunately, most never get to market. The challenge of commercialization is only magnified in the complex, regulated medical markets like medical devices, pharmaceuticals, biotech, and healthcare services. Commercialization processes have great value in medical markets, shortening time to market through planning, managing risk, and maximizing the probability of success. While the complexity can be overwhelming, it can also create significant barriers to entry for competition. The rewards of bring-

ing meaningful products and services to market that help people goes without saying; the personal and professional gratification is at the core of what drives many professionals in this industry.

### Commercialization Symposium

To address the mystery of how to take an idea through the critical phases of commercialization and ultimately to establish that concept as 'the standard of care', LifeScience Alley and the University of Minnesota hosted a full day Commercialization symposium which was held at the U

of M Continuing Education Conference Center on June 9<sup>th</sup>. The program was based on a proven phase/gate commercialization process. The process covers the critical questions to be addressed in each phase, key deliverables, and a gate stage go/no go decision at the end of each phase. The speakers were a seasoned group of successful professionals across all functional areas, from research and development, manufacturing, quality, clinical, regulatory and reimbursement, to marketing and sales. Speakers shared both best practices in the various phases, and case studies of their experiences both as intrapreneurs and entrepreneurs. Program details can be found at: [http://www.lifesciencealley.org/programs\\_events/detail.aspx?id=222](http://www.lifesciencealley.org/programs_events/detail.aspx?id=222). The program will be offered again this winter and prior to the International conference of the Institute of Electrical and Electronics Engineering, Engineering in Medicine and Biology Society (IEEE EMBS) being held in Minneapolis September 2009.

### Commercialization Process: What it is and why should I use one?

A process is not a panacea; nor does it replace hard

work, thoughtful planning, and brilliant execution. It is a tool to structure a plan and ask the breadth and depth of questions that need to be addressed as you develop a product/service from a bright innovative idea into reality.

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### Showcase Your Expertise in LifeScience Alley News

LifeScience Alley is seeking guest-authored content for our monthly newsletter. We encourage our members to consider contributing 1-2 page articles on topics within their expertise. Articles can be written on any life-science specific topic, preferably with a focus on current trends, policies, best practices, etc. We ask that any submission be non-promotional in nature.

Contributors will be given a by-line for their article, which will be circulated to over 8,500 member employees working in 570+ member organizations in all facets of the life sciences. If you are interested in submitting an article or have a particular topic or author to recommend, please download and submit the Newsletter Article Suggestion Form, found here: <http://www.lifesciencealley.org/content/documents/Newsletter%20Article%20Suggestion%20Form%206.25.08.doc> or e-mail [newsletter@lifesciencealley.org](mailto:newsletter@lifesciencealley.org).

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A phase/gate type process has been used by a number of companies in the life sciences like 3M, Medtronic, and Boston Scientific, and a number of smaller companies. While the ‘flavor’ is adapted for each company and business, the overall process has similar tenets. The model we developed was created by combining the best practices from our experiences working with successful and not-yet-successful companies. The discipline that comes from following a phase/gate commercialization process can often be the difference between success and failure. One unique benefit of using a commercialization process is it allows a wide range of functional disciplines to have a common language to communicate with as they go through the fun, but challenging task of developing a new product/service. The process begins with the development of a clear vision, establishment of proof

of concept, and assessment of the market opportunity for the product/service. Next, a business plan is created, including a strategy for all functional areas: R/D, quality, marketing, clinical, regulatory, reimbursement, manufacturing, and distribution. The shared vision and plan allow team members to work toward the common goal. Every new product has unexpected issues during the development; a structured process allows you to manage the issues and minimize the impact on the overall schedule, ultimately speeding your time to market, and time to market adoption.

### What is the value of a phase/gate commercialization process?

Having the right product, in the right place at the right time, and avoiding the common mistake of ‘build it they will come’ is the prize. Time, money, and experience are your most valuable assets in this process. Managing the time and money it takes to

bring a new product/service to market, and maximizing the revenue through strategic market adoption strategies, is the value of using a commercialization process. Ultimately, **maximizing the value of your innovation** is the goal: your great idea reaches the market and has the impact on the patients and physicians that you envisioned.

At a more operational level, the value is beginning with the end in mind, and staying focused on the goal; not letting a million other ideas distract you and the team. The structure of phases, with clearly defined deliverables and gates, cause the key decision makers, either investors or senior management, to make a decision to keep funding the program; it keeps the “train on the track”. The complexity of medical products/services can be overwhelming; with a commercialization roadmap to follow, you can manage the risk, meet the quality

and regulatory standards required by this market, and deliver the product/service in the market window. The process provides the framework for conversations with all of the various contributors to the market and product development; and to develop an integrated plan that results in a product, that truly has impact the day it hits the market, with adequate inventory, key regulatory approvals, the right clinical evidence, publications in key journals, physician advocates, trained distribution organizations, and reimbursement. In closing, it all begins with an unmet need in the marketplace, an attractive market, and a solid business model; however, there is no substitute for strategic business planning and relentless execution.

*In the September newsletter: What are the practical “lessons learned” in using a commercialization process?*

## Commercialization Process: Phase/Gate

