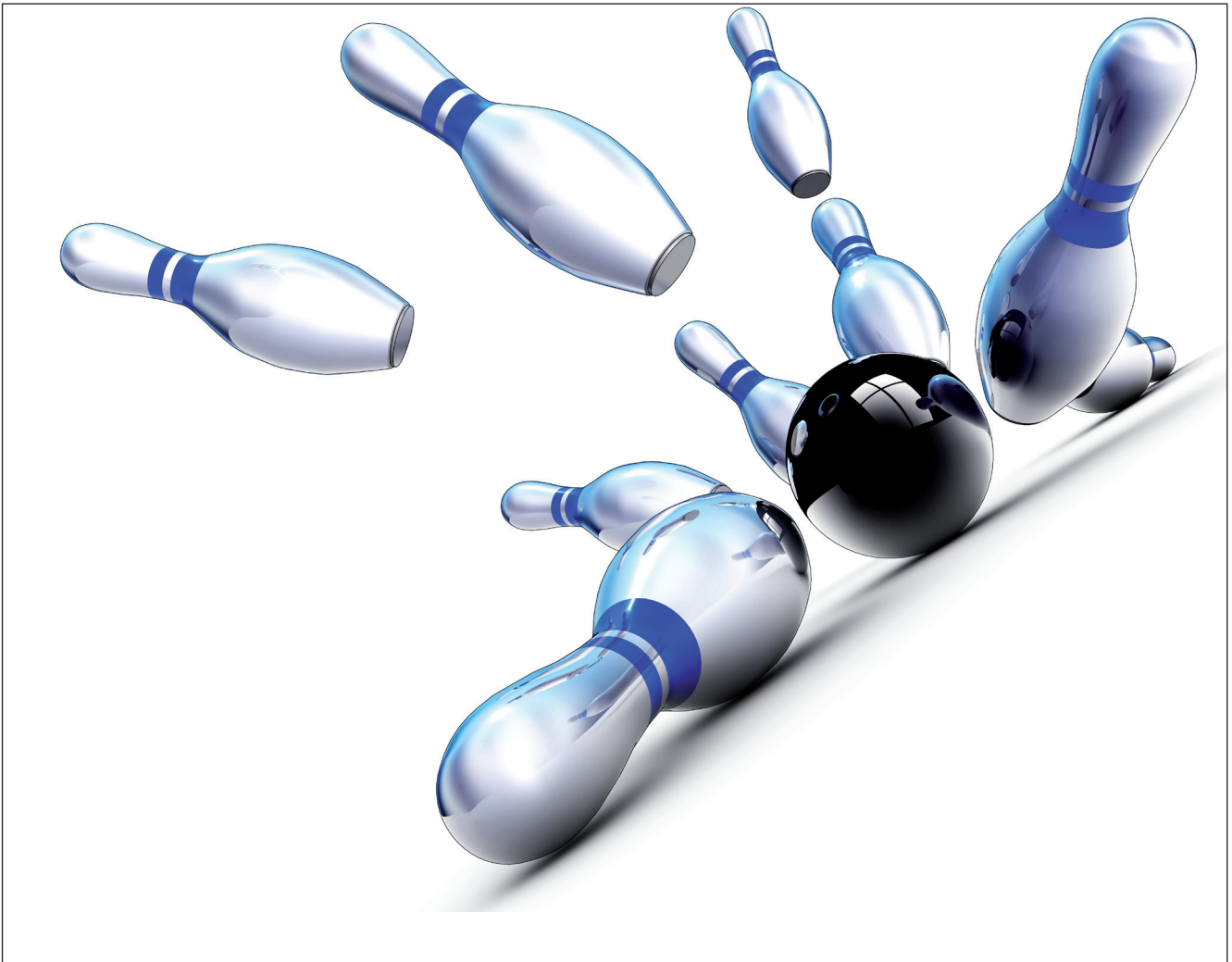


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Know your opportunities

A commercial opportunity assessment can answer many questions when developing a new product

Successful innovation is required to turn good ideas into promising ventures that attract investors, gain regulatory approval, and meet the higher expectations that are common to tough economic times. True innovation, however, appears to be an elusive goal for many companies, if the results of a recent global survey are any indication. While 84 percent of executives surveyed said innovation is extremely or very important to their company's growth strategy, only 55 percent claimed their company is better than their peers' at innovating. These results haven't changed in the last years. Clearly, many companies are struggling with how to be innovative. Here's our take on what pharmaceutical and medical device companies need to do to lay the groundwork for commercially successful product innovations:

Know your market

In previous newsletters/webinars and when working with clients, we've always emphasized that conducting a Commercial Opportunity Assessment is the first step to make in developing a new product, new indication or entering a new market/country for an existing product. It's a critical step. Assessments should be done before getting a patent, determining regulatory strategy, conducting clinical trials or developing a marketing plan. Don't proceed without it.

A well-executed Commercial Opportunity Assessment will give you a complete understanding of:

- ➔ Market profile: What is the prevalence of the condition your product targets in the country where you want to launch, and how does that affect the market opportunity?
- ➔ Definition of the customer: This includes not only who will use the product, but also who will pay for the product.
- ➔ How the product will be used by medical professionals, and how it will be viewed

by payors: How will the product change the treatment paradigm? Will it motivate physicians to change behavior and switch from the current product they have been using for years?

- ➔ Competition: How is your product different or unique, and are these factors meaningful enough to result in a clear differentiation and marketing strategy? How will competitors respond to your product?

Employ an iterative process

If you want to create a product that fulfills an unmet need to the degree that a customer will actually change their behavior enough to buy your new product, our view is that the process to gather the information on what to build is as important as the questions we ask. Truly successful innovation occurs when you take a thoughtful and iterative approach to the entire process. First, start with the basic idea, what you believe is the "unique selling proposition" of your proposed product. Talk to customers and use their feedback to modify the product concept. Then, before you invest more of your company's resources, go back and do it again. Be sure to talk to all categories of potential health care customers, including all providers, institutional buyers and of course, users. When done well, this approach will help you learn what to do to improve your idea with these key customers. It will require discipline and the willingness to give up your assumptions but very impactful. Market feedback almost always indicates the need to adjust your thinking, however minor, away from the original preconceived idea for the product. Sometimes, this feedback dictates a need for a more radical approach – requiring that you pivot or turn the product concept towards a completely new direction.



Every market is different: Be sure you don't commit precious resources that will have been wasted if you find, too far down the path, that your original assumptions were faulty due to incomplete or inaccurate data.

The important thing is to listen to the local customer, and then be willing to make the necessary changes in the product or product idea. Following this iterative process ensures all opportunities and obstacles to market acceptance are rooted out before you go to the expense of completing and launching the product.

Regulatory submissions

In addition to needing a well-funded assessment team with broad experience, success requires a commitment to objectivity and openness. Sometimes the cold hard facts of truth can be painful to accept. Team members have to be focused yet open-minded enough to recognize the signs indicating it's time to rethink product design or the customer offering. You can't wear blinders and ignore signals in the market. If you do, this behavior will ultimately come back to bite you.

There are more than enough examples – and not just in the medical field – of what happens when a management team, even one balanced with commercial and scientific expertise, proceeds too far on their own internal assumptions without adequately listening to the marketplace. One well-known example: Pfizer's inhalable insulin. The company assumed diabetics would rather inhale their insulin than stick themselves with needles. A lot of money was spent developing a device to carry on patients' belts. It wasn't until the product launched and sales were poor that Pfizer recognized that the device was cumbersome and too expensive for doctors to prescribe it.

On the other hand, Addrenex Pharmaceuticals, a start-up company, was a good example that took an iterative approach to assess the precise market opportunity. Their key product development goal was to find the fastest pathway to commercialization.

They began considering that an ADHD indication for their drug would be fastest. But interviewing potential customers and market partners told them that a faster route would be an indication for hypertension. This assessment led to faster commercial progress and a partnership (and eventual acquisition) by Shionogi & Co. Ltd.

Team up with specialists

While focus is important, companies should take care to not commit substantial resources to any one pathway until there is solid market validation for the product. Do not commit precious resources that will be wasted if you find, too far down the path, that your original assumptions were faulty due to incomplete or inaccurate data.

Even when you have an experienced management team, sometimes the addition of an outside specialist can help. Teaming up with an expert that has substantial expertise in conducting commercial assessments and bringing medical products to market can provide these advantages:

➔ **Objectivity:** Enhancing your team's perspective with an outside expert often leads to more accurate insights due to their objective perspective. Internal team

members, for a variety of reasons, may have a tendency to plow ahead ignoring signals from the market.

- ➔ **Faster to market:** Specialists with a toolkit of lessons learned from previous launches can help avoid common mistakes and accelerate time to market.
- ➔ **Flexible expense:** Like outsourcing an engineering design for your new product, teaming up with market assessment and commercialization specialists boosts your capability when you need it, with the ability to cut costs later, when you do not need it. Strengthening your team with a commercialization expert can result in faster time to market along with greater cost savings in the long run.

Remember this

Inventing is about creating ideas. Innovation is about turning those ideas into profitable business ventures. The key to successful innovation begins with an iterative, market-driven approach to assess your product's commercial viability in the particular market. Plus, you need sharp eyes and ears to recognize the signs when you need to revise assumptions and a willingness to do so!

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