

# Your New-Product Roadmap



A PROVEN PROCESS OF ISSUES AND ACTIONS  
TO ADDRESS ALONG THE WAY TOWARD  
COMMERCIAL SUCCESS OF  
A NEW MEDICAL PRODUCT



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# The Roadmap

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**CONSIDER A PROVEN PROCESS**

Your customers likely see your introduction of a new product as a discrete, one-time event. You know better, of course. Any new product is the result of a *process*, and in the case of a medical product a rather rigorous and expensive process.

We have over four decades of experience with this process -- its successes, its failures, its frustrations, and its uplifting moments. The process outlined here is the one we recommend. You might succeed by taking a shortcut or two, but we doubt it!

Whether or not you already participate in a specific market and clinical application of interest, and whether you already have a new-product idea or not, your process should be the same: Consider the proven steps outlined here.

Following any prescribed formula certainly will not guarantee success. Just think of these 8 steps as *reminders* of issues and actions to be addressed along the way to avoid nasty future surprises.

# The Steps

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**FOLLOW A PROVEN PATH  
FROM START TO FINISH**

# 1. Landscape Analysis

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## **Purpose:**

Develop an overview of the target market sufficient to understand the nature and approximate scale of any prospective new-product opportunities

## **Typical issues:**

- What products are currently available?
- What user needs do these various products serve?
- Which suppliers are involved, and how do they rank in influence?
- Who are the buyers, and why do they buy?
- What technologies predominate, and how might that change?
- How large is the domain of interest, and how is its size evolving?

## **Getting it done:**

If you know little to start, or if the consequences are not dire, landscaping is really not so hard. It doesn't have to be expensive or time-consuming because much of the fundamental information you will need has been published somewhere and is free or available for a modest cost. On the other hand, things get dicey when you dive down from 30,000 feet to 5,000 feet; for example when you're trying to determine if a technological upset is imminent or if the consequences are in fact dire (like the survival of your company). Then off-the-shelf information will be harder to find, and you'll have to talk to some "industry experts" and thought-leading users.

# 2. User Needs and Preferences

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## **Purpose:**

Gain an understanding of user needs and preferences in the target market and clinical application

## **Typical issues:**

- What would improve your ability to make better or more rapid diagnoses?
- What changes in therapeutic tools and processes would yield better outcomes for certain patients?
- How easy is it for you to know what to do? Are your required actions obvious or at least easy to learn?
- Could you make a crucial, even life-threatening, mistake? How likely is that? Can that possibility be eliminated or greatly reduced?
- Where does your use of this kind of tool fit into the overall diagnostic or therapeutic process? What might benefit from change, the tool or the process?

These potential questions, while commonly asked, are only examples. A large part of knowing your users is discovering what questions to ask and how best to ask them. Some creativity will certainly be required.

## **Getting it done:**

Users make many decisions intuitively. People aren't as rational as they think they are. They don't have insight into why they do what they do, so asking users to simply explain their choices may yield questionable data. More accurate results may be obtained if you conduct a study by going into the field and observing behavior in the environment of product usage.

# 3. Critique of Existing Products

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## **Purpose:**

Develop an understanding of the positioning of existing products – yours and/or those offered by significant competitors; assess their strengths and deficiencies

## **Typical issues:**

- How do the current products measure up on pricing and value?
- How well, or how poorly, are the products received?
- Exactly what are their deficiencies?
- How might we fix those deficiencies?
- Is it “worth” fixing the deficiencies from a business perspective?

## **Getting it done:**

The required approach is obvious: Dialogs with users (and buyers if different) by various means -- focus groups, interviews, ethnography, surveys, etc.

# 4. New-Concept Development

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## **Purpose:**

Identify a business opportunity, formulate multiple product concepts to serve that opportunity, and hypothetically test the feasibility of each product concept

## **Typical issues:**

- What's our big idea?
- What problem(s) do we intend to solve?
- Who are our prospective users, and what are their relevant needs?
- What product concepts can we imagine?
- How and with whom should we test our concepts?
- What vehicle(s) -- e.g. sketches, mockups, working models -- should we use for testing?
- Is each of our product concepts likely to work and meet relevant user needs?
- Is each of our product concepts feasible to produce, saleable, intellectually protectable, and approvable by regulatory agencies?

## **Getting it done:**

A prescribed formula at this stage is not possible, but the required ingredients include conceptualization, design skills, user empathy, and some awareness of manufacturing methods, IP protection and regulatory strategies. Extensive feedback from prospective users at this stage is essential. The time to kill a deficient product concept is now, not later!

# 5. Prototyping

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## **Purpose:**

Choose a product concept and design direction, then design and build a prototype to prove technical feasibility

## **Typical issues:**

- What's the optimal design approach?
- What are the required and desired product specifications?
- What is the optimal method of fabrication for a feasibility prototype?
- Does the prototype work, and is it acceptable to prospective users?
- Is the chosen product concept patentable?

## **Getting it done:**

Design and fabricate a feasibility prototype based upon the chosen product concept and its performance specifications. Operate the prototype to demonstrate that it works as intended. Expose the prototype to some thought-leading prospective users to validate the design concept and its routine user interactions. File provisional patent applications as appropriate. Finalize regulatory strategy.

# 6. Detailed Design & Development

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## **Purpose:**

Finalize product design and material sourcing, build and test additional prototypes, initiate regulatory design controls, and release the design to production

## **Typical issues:**

- What are the most appropriate production materials, standard components, vendors, and assembly methods?
- What final design and component changes need to be made before production release?
- Is it likely that the final design will be acceptable to prospective users?

## **Getting it done:**

Finalize product design and material sourcing. Build and test additional prototypes as suggested by internal and/or user evaluations. Implement design controls. File non-provisional patent applications as appropriate. Finalize product documentation; release to production.

# 7. Product Launch

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## **Purpose:**

Finalize product and process documentation and product labeling, file for regulatory approvals, and release for sale and distribution

## **Typical issues:**

- Has the production process altered product performance or likely user acceptance in any way?
- Is there any need for additional user/customer/market validation?
- Do the intended pricing structures make sense in light of the cost of goods?

## **Getting it done:**

Finalize product and process documentation. Set pricing. Finalize product labeling and indications for use. Finalize user documentation. File for regulatory approvals. Release the product for sale and distribution.

# 8. Post-Launch Surveillance

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## **Purpose:**

Assess market reactions to our new product, and determine if any additional actions are necessary

## **Typical issues:**

- What feedback are we hearing from the field?
- Do the pricing and value offered match up?
- Are any users claiming confusion in use? If so, can we fix that?
- Are initial sales revenues what we expected? If not, why not?
- Are our competitors reacting or intending to react?
- Should we now take an additional step of some kind?

## **Getting it done:**

Poll the sales and marketing staffs repeatedly for feedback from them, from distributors, and from customers and individual users. Assess the desirability and feasibility of additional immediate actions. Inform the executive team as appropriate.

# The Skills

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**ENGAGE THREE FUNDAMENTAL  
CAPABILITIES TO ACHIEVE SUCCESS**

As you consider the eight steps in this new-product process, three broadly defined capabilities become clear:

- **Understand**: The existing landscape and unmet needs
- **Imagine**: Potential solutions
- **Realize**: A new product in user hands

These three capabilities correspond to three different, equally important skills that must be brought to bear. You must engage each of them in turn. If they are not all available in-house, you must reach out and engage outside experts as needed.

If you choose to reach out, we can help -- either directly or in collaboration with our affiliates in new-product design, development and commercialization.

Start a conversation:

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