FROM IDEA TO PRODUCT
HOW NEW MEDICAL DEVICES HAPPEN

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I have this great idea for a new wadigitator!

Wonderful! Here is $100M!
I have identified a significant opportunity! Surgeons need a way to walmulate and none like their current method! The wadigitator device I conceived solves this problem and is easy to manufacture!

Interesting! Keep me informed as you move this idea along!
Getting Over the Hurdle

• Is the opportunity significant?
• Is the technology proven in animals?
• Can it be manufactured?
• What do the physicians think of it?
• What is the patent protection?
• Is there a defined regulatory path?
• What is the competition doing?
Innovating in the Med Tech Space
innovation

Ideas that add value to society
What’s Emerging in Med Tech

- TAVI
- Hi Tech Prostheses
- Artificial Retina
- Neuromodulation
- Surgical Robots
- BMI
Med Tech Market Size

Products and services segmentation (2012)

- 36% Other medical and therapeutic devices
- 22% Spinal devices
- 18% Cardiovascular devices
- 10% Neuromodulation devices
- 6% Diabetes devices
- 5% Urology devices
- 3% Surgical technologies

Total $64.7bn

SOURCE: WWW.IBISWORLD.COM

Major players
(Market share)

- General Electric Company 12.9%
- St. Jude Medical Inc. 4.2%
- Medtronic Inc. 14.8%
- 68.1% Other

SOURCE: WWW.IBISWORLD.COM
Medical Innovation Drivers are Changing

Old

Clinical care rules
Make what docs want
Cost doesn’t matter

New

Economic value
Better outcomes at same or lower cost
Global market
Med Tech Trends

• Diagnostics that guide therapies
• From lab to desktop
• From clinic to home
• Direct-to-patients apps
• Minimize hospital stay
• Less invasive
• Device + biologic combination
• Increased value for $
• Physicians relieved of routine work
• Evidence based practice
Med Tech Development is Not App Development

“it's going to cost on average $150 million to get a company through the entire PMA [pre-market approval] process.”

“Your [exit valuations] have to be $500 million or more to make the economics make sense.”

Source: VC Roundtable, The Collaborative, Star Tribune, 04/2012
Basics of New Product Development
Med Tech Development Process

Rough Sketch
Animation
Prototype
Bench Testing
Animal Testing
First in Human Testing
Clinical Trial
Product Launch

Internal Financing
Angels
VC
Buyout

PMA (FDA)
Med-Tech Innovation Process

Understand the opportunity
- Disease state
- Current solutions

Define the need
- Know the customer
- Observe

Create the solution
- Invent!

Build and Test
- Prototype
- Test
- Screen
- Repeat

Carrying On
- Startup
- Exit

IDENTIFY | INVENT | IMPLEMENT
Most Ideas and Many Products Don’t Make It

- Focus on features v. benefits
- Not understanding the market
- Optimistic sales ramp up (< 3 yrs)
- Too far out there (Segway)

Source: www.pdma.org
Needs Driven Innovation

You may have the answer

But do you know the question?
What Type of Idea Do You Have?

TECHNOLOGY-DRIVEN

Technology push

Technology searching for an application

NEEDS-DRIVEN

Idea

Market pull

Customer demands it.
Finding the Needs
Understanding Customer Needs

“That doesn’t mean we don’t listen to customers, but it’s hard for them to tell you what they want when they’ve never seen anything remotely like it. Take desktop video editing. I never got one request from someone who wanted to edit movies on his computer. Yet now that people see it, they say, ‘Oh my God, that’s great!’”

- Steve Jobs, Fortune, Jan. 2000
How to Find the Real Needs

• Understand the disease state
• Research current practice
• Immerse yourself in the environment
  – Observe
  – Ask questions
• Conduct one-on-one interviews
  – Probe to find the pain points
• If you are the physician-inventor, determine if others have the same problem
• Look for the problem, not for the solution
Determine the Customer

Hospital Admin

- CEO
- CFO
- Purchasing Agent
- Cardiovascular Services Manager
- Cath Lab Manager

- Physician
- Nurse
- Patient
- Caregiver
## Market Research Methods

### Qualitative
- To measure what customers are thinking and why
- One-on-one interviews and observations
- Data reported using summary statements and customer quotes
- Used in early stages of project

### Quantitative
- To measure how many
- Large sample surveys: online, mail, telephone
- Data reported using summary statistics
- Used in later stages of project
Interview Methods

• Determine the research **objective**
  – What do you want to get out of the interview?

• Determine interview targets
  – Job description, level of experience
  – Who you want to talk to and who you don’t want to talk to
  – Key opinion leaders may only represent 5% of the market

• Find interviewees

• Prepare the interview guide

• Conduct the interviews
  – Probe for the pain points
  – Follow up to understand the whys
    • “What do you mean by _____ ?”
    • “Tell me more about _____?”

• Analyze and report results
Creating Solutions
Generating Ideas

Brainstorming

Solo-storming

Borrow

GOAL ➔ 100’s of ideas
The more ideas you have the more good ideas you will have
Screen the Ideas


Iterate
Build Your Idea

“I have an idea for an engine that gets 80 mpg”

That’s nice, show me!

- Prototype to learn
- Prototype to communicate

A working prototype will sell your idea
Prototyping
Virtual Prototyping
Test Your Solution
Start by Bench Testing Your Device

- Optimize product design
- Simulate various clinical anatomies
- Accelerated wear testing
- Ongoing verification as to the utility of a technology
- Freeze design before pre-clinical studies are initiated
Animal Model Testing

• To validate efficacy of a device within an appropriate animal model.
• To validate device in real anatomy and physiology
• To obtain outcomes and safety data needed for 510(k) submissions or for developing human clinical trials
• To obtain biocompatibility data
• To gain confidence in the technology itself
Clinical Testing

• Why
  – To test elements of clinical practice
  – To justify clinical decisions
  – To optimize the device
  – To provide safety and efficacy data for FDA submission

• Types
  – First-in-man (FIM)
  – Randomized clinical trial (RCT) $$
Projecting if money will be made
Key Estimates

• Product cost
• Product price (value-based)
• Market share (over time)
• Development costs
Adoption Rate of Consumer Electronics

## Pro Forma Financials Seen in Many Startup Business Plans

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales (units)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y1</td>
<td>20,000</td>
</tr>
<tr>
<td>Y2</td>
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<tr>
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<tr>
<td>Y4</td>
<td>20,000</td>
</tr>
<tr>
<td>Y5</td>
<td>20,000</td>
</tr>
</tbody>
</table>

### Graph

![Graph showing sales over years](image-url)
Early Stage Financial Model

• Be explicit with assumptions
• Cite credible sources for data
  – Peer reviewed literature
  – Government reports
• Provide a range
  – Likely, Optimistic, Pessimistic
• Be realistic about market share
  – “We think our product will in 5 years capture 10% of the market”
• Use an analogous product to estimate cost, price, trends
• If early stage, your numbers will be ignored
Protecting Your Idea
Intellectual Property Is Essential

- Patent protection is essential to med tech development
- Value of startup is its people and its patents
Regulatory and Reimbursement
Regulatory boards require evidence to support claims that a technology is

• Safe (Europe, CE mark)
• Safe and effective (U.S., FDA)

**FDA Device Class**

- **Class I (low risk)**
  - FDA exempt: register but no clearance needed
- **Class II (moderate risk)**
  - 510(k) path: follow a predicate device
- **Class III (high risk, life sustaining)**
  - Pre-market approval (PMA) path: expensive, clinical trials
FDA Design Process

DESIGN CONTROL GUIDANCE
FOR
MEDICAL DEVICE MANUFACTURERS

This Guidance relates to
FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001

March 11, 1997

www.fda.gov

III. APPLICATION OF DESIGN CONTROLS

Design controls may be applied to any product development process. The simple example shown in Figure 1 illustrates the influence of design controls on a design process.

![Diagram of Design Control Process]

Figure 1 – Application of Design Controls to Waterfall Design Process (figure used with permission of Medical Devices Bureau, Health Canada)

The development process depicted in the example is a traditional waterfall model. The design proceeds in a logical sequence of phases or stages. Basically, requirements are developed, and a device is designed to meet those requirements. The design is then evaluated, transferred to production, and the device is manufactured. In practice, feedback paths would be required between each phase of the process and previous phases, representing the iterative nature of product development. However, this detail has been omitted from the figure to make the influence of the design controls on the design process more distinct.

Introduction 3/1/97
Reimbursement is Essential

Requires evidence to support claims that a technology leads to better patient outcomes at lower cost than existing solutions
Financing Your Project
Why Investors Matter

• Investors move money from those who have it (the investors) to those with the ideas (you)
• Investors can take the risk
What Are Investors Seeking?

• Disruptive technology
• Chronic disease solutions
• Markets > $1B
• Clear regulatory path
• Clear reimbursement path
• Potential for product platform
• Strong management team
Recognize the Contrast

What Inventors Think About

- Solving *my* problem
- Get out fast
- Get rich

What Business Thinks About

- Time
- Cost
- Risk
Non-Traditional Funding Sources

Government grants
SBIR/STTR (U.S.)

Crowd funding
Pitching Your Idea

- Know your audience
- Know what you are asking
- Know your technology
- Know your competitors
- Have 5 second, 30 second and 30 minute versions
- State your goal
- Leave ½ the time for discussion
- Be enthusiastic
Why Don’t Investors Like My Idea??

• Market size
• Incremental technology
• Uncertain regulatory approval
• Uncertain effectiveness
  – Dubious reimbursement
• Not a strategic fit
• No evidence that it works
• No prototype
• No one else is excited
Wrap-Up
Always Keep the 3 F’s in Mind

- Market Feasibility: Does anyone want it?
- Technical Feasibility: Can we make it?
- Financial Feasibility: Will it make $?

Is it a strategic fit to the organization?
Why *You* Matter

- Companies look to physician inventors and universities for new ideas
- Most innovation comes from the user
What Is a Simple Process For Me?

Find the problem

Invent the solution

Implement and test