The Challenges of Medical Device Development

Moving from the lab to the consumer

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Discussion Agenda

I. Overview of Continuum Advanced Systems

II. Presentation and Discussion
   Key elements of success for commercializing a medical device

III. Case Study
Continuum Advanced Systems works at the intersection of technology, systems, and human-centered design. Our expertise is in understanding needs, behaviors, and environments and then developing systems and technologies that people value.
Locations and Recent Medical Fieldwork

- **North America**
  - Boston, MA
  - Worcester, MA
  - Stonington, CT
  - Providence, RI
  - New York, NY
  - Philadelphia, PA
  - Pittsburgh, PA
  - Washington, DC
  - Norfolk, VA
  - Montreal, CAN
  - Cleveland, OH
  - Columbus, OH
  - Youngstown, OH
  - Ann Arbor, MI
  - Chicago, IL
  - Houston, TX
  - Albuquerque, NM
  - Portland, OR

- **Europe**
  - Paris, France
  - London, UK
  - Southampton, UK
  - Leeds, UK
  - Berlin, Germany
  - Frankfurt, Germany
  - Rome, Italy
  - Monza, Italy
  - Milan, Italy
  - Genoa, Italy
  - Madrid, Spain
  - Oslo, Norway

- **Asia**
  - Tokyo, Japan
  - Yokohama, Japan
  - Hong Kong
Snapshots of past projects

**INSULET**
Freedom delivered
Insulin management & delivery

**DATASCOPE/MINDRAY**
Critical care
Patient monitoring

**AVEDRO**
Lasik alternative
Vision correction

**GENERAL DYNAMICS**
Safety and Integration
Designing for the Soldier

**SIEMENS (DADE BEHRING)**
Testing system
Blood analysis, workflow

**NOMIR**
Laser precision
Podiatry treatment
Expertise

- Contextual Research
- Industrial Design
- Human Factors / Ergonomics
- Mechanical & Optical Engineering
- Validation and Usability Testing
- Electrical Engineering
- Modeling and Prototyping
- Alliances, Collaboration and Project Management
- Systems Engineering
- Interaction Design & Software Development
- Systems Engineering
Client breadth (Health & Medical space)
Business success

**REEBOK / Pure Innovation**
Double Sales to $2B

**BOSE / Aviation X-Headset**
Best Seller

**BMW / Interaction Design**
Driving Innovation

**MASTERLOCK / Security vs. Locks**
Breaks Low Cost Cycle

**Swiffer / Enabling Aspirations**
Creates New Category

**MIT MEDIA LAB / Enabling Education**
Revolution by Design
Challenges of Medical Device Development

Critical Areas of Focus:

- Strategy
- Delivery
- Relationships
What’s the game plan?
• Business strategy and priorities
For early stage companies, what’s the end game?
What’s most important?
(TTM, functionality, cost/price)
Is this a consumable, service or device business?
Distribution, product roll-out, what countries?

• Regulatory Strategy
What is our submission strategy?
What is the clinical strategy?
510k, PMA, FDA relationship
Strategy

• Risk management and contingencies

Expect surprises (IP, people, technical, etc.)
Don’t over commit

• Insurance reimbursement

How are you analyzing this?
Are you taking advantage of emerging opportunities?
Delivery

Critical Areas of Focus:

• Strategy
• DELIVERY
• Relationships
Delivery

What’s it going to take to develop and deliver this?
Delivery

Organization

*Key roles*: Business, Marketing, Product Development, Quality, Science

Decision Making

What will be the basis for decisions?
Consumer or stake holder perspectives rule?
Who is really empowered?
Delivery

• Development Process
  Fun, challenging, messy
  No perfect product – EVER!
  Think in terms of generations – not completion
  Technology development – understand robustness
  Product Requirements – maturity and impact

• Development Path
  Straight verses curvy
  (Hint: Straight never happens!)
  Sometimes loopy…
• Vocabulary

What words are used by development teams
“Design language”
“Works like, looks like model”
“Full function, alternate process”
“Architecture, concepts, detailed drawings”
Always ask what “prototype” means!
Relationships

Critical Areas of Focus:

• Strategy
• Delivery
• RELATIONSHIPS
Who, within your organization, is going to own the key relationships with outside resources?
Relationships

- **IP, Licensing, & Contracts**
  Often not the same resource
  Outside or inside counsel?
  Contract Terms – Flexibility and Risk
  T&M, Fixed Price, COS

- **Regulatory Affairs**
  FDA, UL, CE, etc.
  Testing and Certification
Relationships

• Development Partner
  Who will manage day to day contact?
  Technical or development experience?
  Risk Management and expectations

• Manufacturing Partner
  Strategic decision
  Early selection is key
  Offshore or domestic?
  Volumes & cost
Case Study: Insulet

OmniPod™

Insulin Management System
Insulet: Company facts

• Venture funded start up company in Bedford, MA
• Began with 4 key employees (Marketing, Engineering, Regulatory, Business)
• Started with an idea
• Commissioned some technology work
• Built internal **and** external team
• Took 2 years to develop
• Received 510(k) approval in Feb 2005
• Now 300+ employees, clean room manufacturing operations, and making a big splash
• Went public in 2007 and are extending the technology to deliver other drugs
Areas of design and development

- Interaction design
- Pod design
- Controller (PDM) design
Insulet OmniPod technology

Previous insulin infusion technology

“I’m sick”

“I’m just like you”
Immersion and learning

The project commenced with learning: diabetes is a complicated disease, and bringing the desired experience to the user required the team to lean a lot about it.
Product behavior: Considerations

The team considered the physical side of the system, everything from how to control complex interaction functions to the pump itself, and how it might attach to the body.

Painful Adhesive
Translating User Insights

- **Remote Criteria**
  - **Active Feel**
    - Strap Detail
    - Rubber/Texture Wrap
    - Color
  - **Pocket Life**
    - Button Access
    - Possible Pocket Bows Through Pants
    - Slide Into Pocket
    - Pocket Positioning Harness
    - Button Protection
  - **Cool Posture**
    - Button Placement
    - One Handed
    - Techy Movement/Angles
  - **Communication w/Pump**
    - Lights
    - Antenna
  - **Reference to Pump**
    - Size
    - Color
    - Materials
    - Shape

- **Where does remote live?**
  - **Belt**
    - Aesthetics - signal that you are a pump wearer (signs)
    - Does wearing it on your belt create a perception that it is just for other pumps?
    - Why does it matter that the pump is small when you have to wear a large remote on belt?
    - Weight - not as many bottles [or pumps]
    - Can you access remote while on belt, or do you need to remove it to interface with it?

- **With stuff**
  - **Remote**
    - Remote to palm
    - Remote to purse
  - **Compartment (round disk)**
    - Tactile buttons
    - Collapsible buttons?
    - Sound - more to attention
    - Size - longer & thinner vs. square
    - Women - less pockets (but maybe purse)
    - Vibration option
    - Pocket clip?
  - **With diabetes stuff**
    - You carry stuff around all day anyway - why not carry remote?
    - Asset tracking
    - Very robust
    - Other use?
Key to the design effort was a prototype of the device, which ran on a PC and allowed the team to test navigation, understand how the information was distributed, etc. This prototype was also used by the client for demos and board meetings.
You are using the new pump system to manage your diabetes. Please use the prototype to perform the following tasks.

1. Turn on the device and determine the amount of insulin currently being delivered.
2. You are about to eat a meal of 30 grams of carbohydrate, and your blood glucose is 110. Use the device to give yourself the proper amount of insulin.
3. You are about to spend some time exercising briskly. Reduce your basal rate by 35% for the next hour and a half.
4. You have decided to stop exercising early. Return your basal rate to its usual level.
5. Your blood sugar level is 185; deliver a correction dose to bring your level down to your target of 120.
6. Now, your blood glucose level is low. Suspend delivery of insulin for one hour.
7. Now you decide to resume delivery of insulin.

8. What was your blood sugar level at dinnertime on March 24?
9. How much insulin is left in the pump?
10. Time for another meal. You are about to eat a meal containing 27 grams of carbohydrate, and your blood sugar is now 160. Use the system to give yourself the proper amount of insulin.
11. Your educator recommends that you visit Dr. Foot, a podiatrist. His phone number is 617-969-5400. Enter his name and number into the “Healthcare Team” section of the device.
12. You eat a cookie; without bothering to check your blood sugar level, give yourself a bolus of 0.2 units.
13. Adjust the basal rate for the device so that 0.9 units/hr are delivered between 3am and 6am.
14. Now, adjust the basal rate for the device so that 1 unit/hr is delivered between 5am and 8am.
Early R&D and technology development

Miniature actuators: custom and off-the-shelf
Technology Development: Pod

- Custom wireless
- Novel mechanical functionality
- Design for manufacturability
- Regulatory approval
- Efficient power
- Novel auto insertion
Pod user interface: Research informing the design

How should the cannula be inserted?

Manual, simple  Automatic, complex
Insulet OmniPod

Previous insulin infusion technology

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Insulet OmniPod technology

“I’m just like you”
Insulet Summary: Strategy, Delivery, Relationships

OmniPod

Insulin Management System
Challenges of Medical Device Development

Critical Areas of Focus:

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Thank you.