Taking Control of Your Fuzzy Front End

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Agenda

Measuring Success

IPM Case Study

Discussion
What Defines a Successful Product Launch?

- Faster Time to Market
- Meets Users Needs
- Better than 3x VC ROI
- Successful Launch
- Increases Market Share %
- No product recalls
- Reduces Healthcare Costs
- Improves Patients' Lives
- Compliant Process
Successful Launch

Product Development Timeline

Idea → Launch

Main efforts spent on ensuring a successful device product launch

Whether a device launch is successful is determined much earlier in the product development timeline
Top Six Reasons for Product Failure

- Unrealistic schedule expectations
- Product does not meet customer or market requirements
- Unclear or continually changing product definitions
- Unrealistic financial expectations
- Unclear or continually changing priorities
- Projects not adequately staffed

Aberdeen Group, August 2006
Main Sources for New Product Ideas

- Customers: 88%
- R&D: 77%
- Marketing: 75%
- Sales: 52%
- Other employees: 43%
Uncovered

Timing of Activities

Balance of Activities
Transforming Global Product Development

**Background**
- Fortune 500 Medical Device / Diagnostic Company
- R&D Centers and outsourced Operations in US and EU
- Quality, Sales / Marketing, Regulatory primarily US based
- Portfolio of Class II and III Devices

**The Issue**
- Products delayed to market
- Products did not meet all of the user needs
- Strong need to increase R&D throughput

**The Objective**
Get more products to market faster which meet the requirements of the end user.
Initial Assessment

- Products delayed to market
- Products did not meet all of the user needs
- Strong need to increase R&D throughput

Lack of Portfolio Governance

Over utilized R&D group

Development time for IVD’s >>> industry averages

Lack of **disciplined** approach to product development

Passive Voice of Customer (VOC) feedback process

Development effort >>> market research effort

Significant # of products in development
Current Product Development Process

- Lack of control in critical upfront processes
- Development time for IVD’s >>> industry averages
- Lack of disciplined approach to product development
- Passive Voice of Customer (VOC) feedback process
- Development effort >>> market research effort
Welcome the Fuzzy Front End

Key activities between Idea Generation and Formal Development

Fuzzy Front End

Provides key information to facilitate Go / No-Go decisions

Formal Development (i.e. Design Control)

Development / Design Transfer

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Consider / Re-consider the Fuzzy Front End

- Products can fail due to technical hurdles, but most likely due to lack of true market
- New products have very high failure rates

Myth
Moving Ideas straight into Development reduces time to market

Reality
- Average durations for Development can be much longer due to Verification and Validation (Formal Development) being an experimental exercise
- Products are launched into non-existent markets or not meeting all of the user needs
Step 1
Idea Screening

Management Go / No-go Approval
Market Opportunity Assessment

What is the application or concept?
What is the high-level value proposition?
Who are the main competitors?
What initial markets are we targeting?
Freedom to Operate (FTO)

Patent Landscape of "Blackberry" Patent Lawsuit

Landscape Map™ of the "Starbucks Coffee Sleeve" Patent

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Freedom to Operate (FTO)

- High-level patent landscape (lifecycle document)
- Determine best mix of outside (IP expertise) / inside (product insights) counsel
- Build a proactive, participatory relationship throughout the lifecycle
Regulatory Assessment

- High-Level Regulatory Assessment
- Preliminary regions forecasted to understand regulatory pathways and hurdles
- Closely tied with FTO and Market Opportunity Assessment
- Build a proactive, participatory relationship throughout the lifecycle
Portfolio Assessment

- Portfolio mix
- R&D throughput
- Development priority

Clinical R&D Resource Forecast

- Clinical R&D Resources (Project X)
- Clinical R&D Resources (Cumulative Project Demand)
- Clinical R&D Total Headcount

[Graph showing resource forecast with months from Feb to Aug]
Initial Wins

Market landscape had significantly changed since inception

One Customer Data Point

Risk >>> Return

Skunkworks Project
Concept Stage (Idea Screening)

Market Research
- What is the Application or Concept?
- What is the Value Proposition?
- Is there a clear market needs?

Strategy
- Business Alignment
- High-Level Regulatory Assessment
- Preliminary Freedom to Operate (FTO) Assessment
- Portfolio priority

Technology
- High-Level Technological Assessment

Management
Go / No-Go Approval
Provide **focus** to the organization resulting in the best chance of success in getting the **right** ideas into development and commercialization.
Formal Development (V&V)

Move into Formal Development?

NO!

Commercial
What exactly are we making?

Technical
Design Control
Proof of Concept
A Delicate Balance

Commercial

Technical

Concept
Market Research

![Market Research Chart](image)

### Attribute Relative Importance

<table>
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<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
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<th>I</th>
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<td>19.2</td>
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<td>6.0</td>
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### Differentiation

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<th>Factors</th>
<th>Variables</th>
<th>Importance Rating*</th>
<th>Benchmark Performance</th>
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<td>Safety</td>
<td>Major Complication Rates</td>
<td>40%</td>
<td>Product X</td>
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<tr>
<td>Effectiveness</td>
<td>Device Success Rate</td>
<td>25%</td>
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<td></td>
<td>Procedural Success Rates</td>
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<tr>
<td>Ease of Use</td>
<td>Deployment Time</td>
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<tr>
<td>Patient Comfort</td>
<td>Pain Level</td>
<td>15%</td>
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<tr>
<td></td>
<td>Patient Request</td>
<td></td>
<td></td>
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<tr>
<td>Price</td>
<td>ASP Target</td>
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Reimbursement Strategy

“...a thorough reimbursement strategy has become as important as the FDA strategy in the success of a new device.”

“Only 26% of the companies indicated that reimbursement was part of the formal product lifecycle development process”

<table>
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<tr>
<th>Challenges to Buy-in on Reimbursement Issues</th>
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<tr>
<td>Lake of awareness of potential consequences of reimbursement barriers       50%</td>
</tr>
<tr>
<td>Inadequate authority of the reimbursement function                           26%</td>
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<tr>
<td>Inadequate support from senior executives                                      16%</td>
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<tr>
<td>Inadequate support from CEO                                                    8%</td>
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Reimbursement Strategy

Coverage
- Determines eligibility for payment for products & services

Payment
- Payment processes and amounts

Coding
- Classifies patient conditions, services and supplies required

Product Development Timeline

Idea
- Reimbursement Research & Strategy

Clinical Studies
- Focus on demonstration of enhanced outcomes and cost effectiveness

Launch
Reimbursement Strategy

The Global Impact
Proof of Concept

Select Partners

Prototype Testing

Concept Selection

Market Research / VOC

Device Attributes

Clinical Study Assessment
Feasibility Stage

**Market Research**
- Detailed Market Assessments
- Key Opinion Leaders
- Medical / Scientific Boards
- Initial Reimbursement Data
- Health Economics

**Technology**
- Prototype Development and evaluation
- Initial Manufacturing Assessments

**Strategy**
- Clinical Strategy
- Pre-Submission Meetings
- Supplier Assessments
- Continued FTO Evaluation
- Publication Strategy

**Requirements**
- Product Requirements (Design Inputs)
Solidify the business case of the idea by capturing more robust product requirements and intended uses through detailed market research and proof of concept evaluations.
Formal Development (V&V)

Move into Formal Development?

**NO!**

What we are building **does not guarantee** how we are building it
Planning

**What**
- Design and Development Plan
- Deliverables Matrix by Stage
- Design History File

**Who**
- Roles and Responsibility Matrix
- Decision Rights

**When**
- Detailed project schedule
- Critical path assessment
- Acceleration opportunities

**How Much**
- Detailed Budget Assessment

**Any Risks?**
- Risk Management Process

**Feedback**
- VOC
- IP
- Regulatory
- Stage Gate Reviews
- Design Reviews
Prior to entering formal development, ensure adequate preparation has been completed to increase the chances of developing and launching a successful product.
The fuzzy front end can consume up to 50% of development time and it is where the course for the entire project and final end product are set.

Formal Development (V&V)

Move into Formal Development?

YES!
Client Impact

Client was not VC funded; however, was viewed as a stronger partner in Dx / Rx relationship

- Faster Time to Market
- Better than 3x VC ROI
- Meets Users Needs
- Increases Market Share %
- No product recalls / complaints
- Reduces Healthcare Costs
- Improves Patient’s Lives
- Compliant Process
- Successful Launch

None identified
Key Takeaways

• $$$$ and TTM are just a few factors determining product launch success

• Investigate

• Educate
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