

Product Realization Group
Webinar Series

Product Feasibility

.... Annuvia case study, understanding product readiness

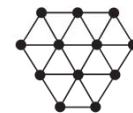
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Product Realization Group[®]
Bridging the Product Development Gap

Where does Feasibility Fit?

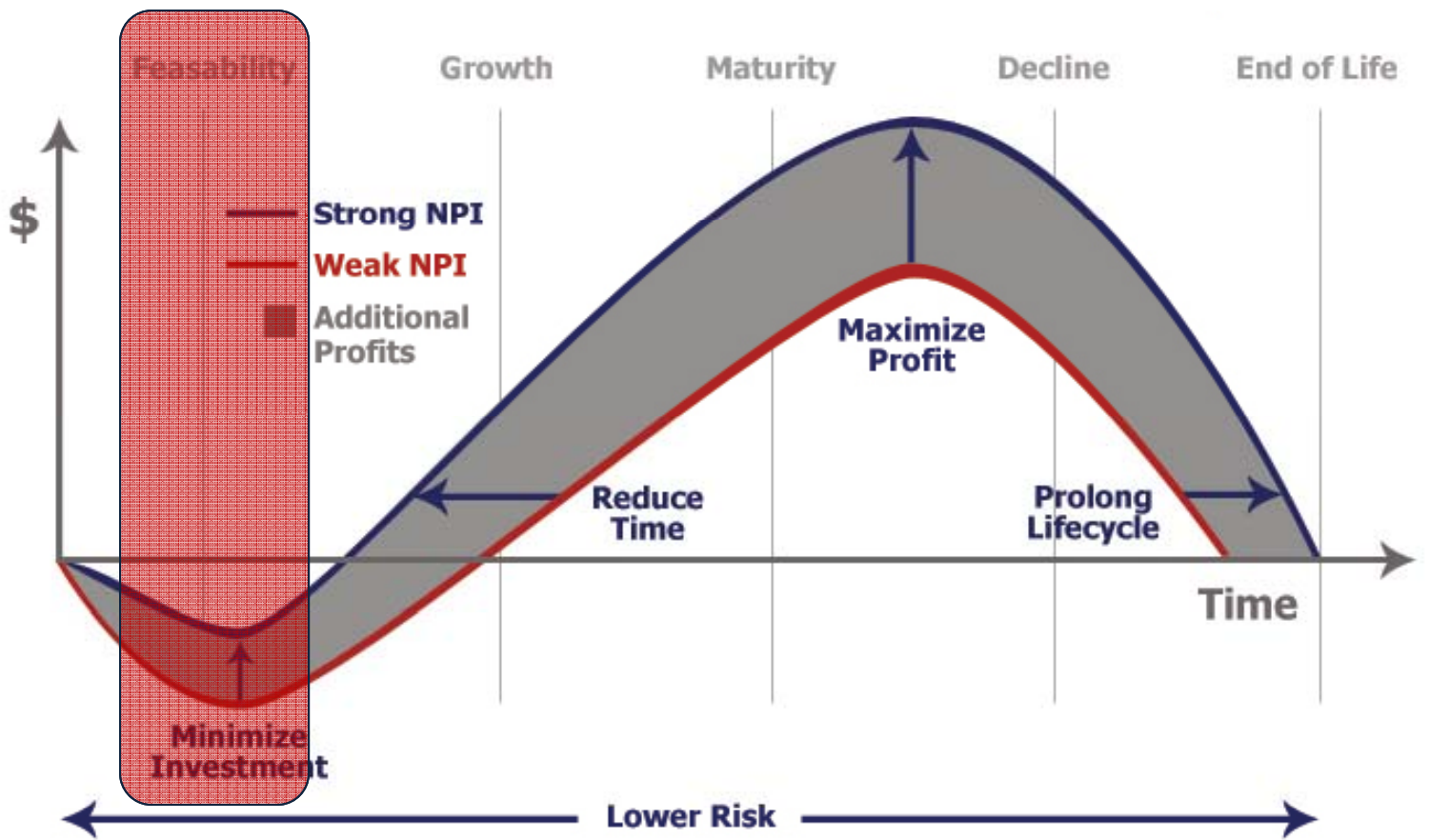
Product Lifecycle

Follows a product from concept to end-of-life



Feasibility is a subset of the product lifecycle, and focuses on understanding the **readiness to move a product into development**

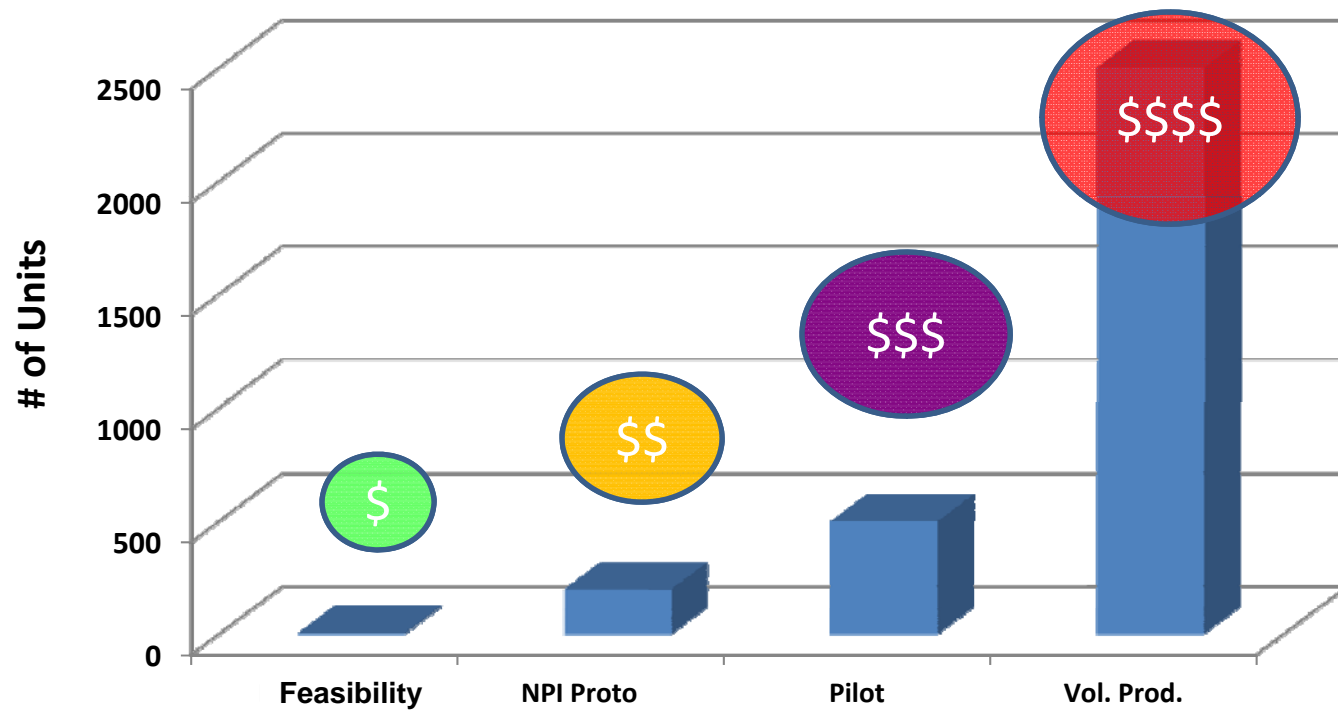
Impact of Feasibility in the Product Lifecycle



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Importance of Feasibility in the Product Lifecycle

Escalator Effect



Do it right from the start -
The leverage is HUGE!

Speakers

Micah Bongberg

Is the President and CEO of Annuvia. Annuvia is one of the leading health, safety, emergency preparedness, and emergency response organizations in the United States.

Michael Keer

Is the Founder and CEO of Product Realization Group. The PRG enables rapid and cost effective introduction of products to the market, regulatory compliance, manufacturing, service, and lifecycle support.

Speakers

Mark Brinkerhoff, PE

Is the President of Fusion Design. Fusion provides mechanical development services for medical, industrial, recreational and many other product applications

Walt Maclay

Is the President of Voler Systems. Voler provides electronic design and software services for medical, industrial, aerospace and instrumentation applications.

Feasibility Tips

- ❖ Identify risks early (regulatory, technology, manufacturing, etc.)
- ❖ Evaluate multiple solutions
- ❖ Use known & easily available technology



Feasibility Tips

- ❖ Consider emerging technologies & markets
- ❖ Weigh evolutionary vs. revolutionary
- ❖ Choose scalable solutions
 - ❖ Technology
 - ❖ Manufacturing





BEACON PRODUCT FEASIBILITY: CASE STUDY

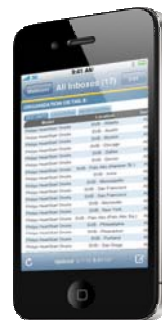
AED Industry Background

- ❖ Sudden Cardiac Arrest (SCA) is the leading cause of death in the United States
- ❖ Automated External Defibrillator (AED) units provide a therapy that can save the majority of victims (+70%)
- ❖ Time is of the essence: Victim loses a 10% chance of survival for every minute that passes



Arch Software: What Does it Do?

- ❖ Maintains records for AED owners, distributors, and manufacturers
- ❖ Registers units with local EMS or 911 dispatch
- ❖ Oversee records by a licensed MD
- ❖ Send AED owners reminders to update equipment



The Beacon Product Concept

❖ Integrates with Arch

- ❖ Turns our “static” database “dynamic”

❖ Live Feedback

- ❖ Automatically “reads” an AED’s status
- ❖ Accurate AED location/placement data
- ❖ Notification Instant AED is opened

❖ Additional features (remote updates)

- ❖ Voice to connect rescuer with 911 operator
- ❖ Temperature monitoring



Now What?

- ❖ Toe the market opportunity while testing feasibility
- ❖ Understand all risks and expenses (to build, produce, and operate)
- ❖ Does the market opportunity exceed the costs? How soon will we break even?

Is it Feasible?

- ❖ Regulatory Environment
- ❖ Technology
- ❖ Time-to-Market
- ❖ Manufacturability
- ❖ Costs



Regulatory Environment

- ❖ What class medical device would it be?
 - ❖ AED is class III, most highly regulated
- ❖ Extra cost of developing a medical device can easily double the cost
 - ❖ Quality system
 - ❖ Regulatory paperwork
 - ❖ FDA filing
 - ❖ Waiting for FDA response

Determining Regulatory Status

- ❖ Getting FDA to give definitive advice before a product is developed is very difficult
- ❖ PRG regulatory partner has experience working with FDA staff
- ❖ Was able to get an email stating the proposed product would not be a medical device
- ❖ Huge savings in time and money

Technology: Feasibility Approach

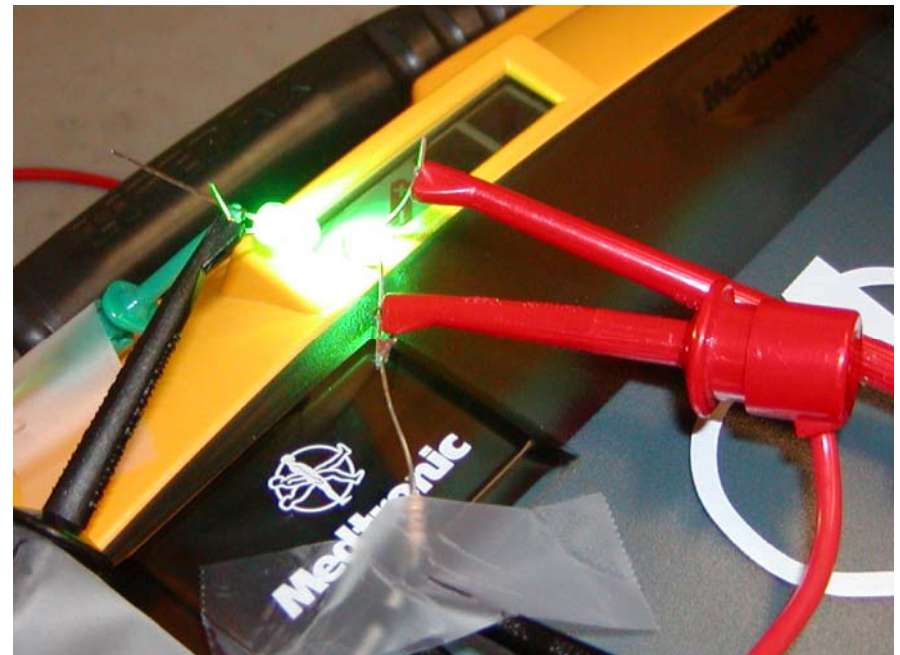
- ❖ Define key methods of detection
- ❖ Design a test set up
- ❖ Build
- ❖ Test and submit results
- ❖ Update test set up per feedback
- ❖ Test
- ❖ Report feasibility findings
- ❖ Update Product Requirements Document (PRD)



Technology Feasibility

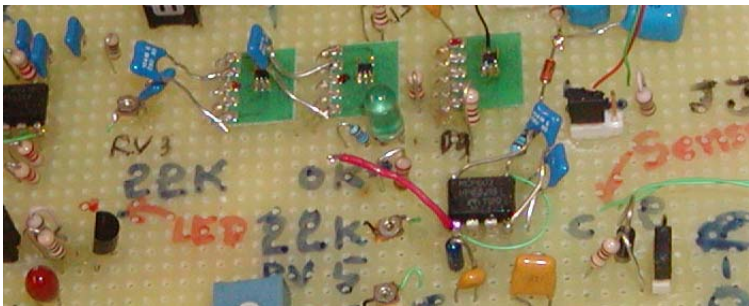
Product Requirements

- ❖ Sense a message on LCD display
- ❖ Photosensor with LED illumination is simple, low cost detector
- ❖ Wide range in ambient light – dark to full sun
- ❖ Can't obstruct view of LCD display
- ❖ Wireless data transmission
- ❖ Low power consumption
- ❖ Quickly open and replaced electronics
- ❖ Mechanical alignment



Technology Feasibility - V1

- ❖ Built simple circuit & mechanical mock-up to test detection of warning
 - ❖ Tested in direct sunlight
 - ❖ Tested in full darkness
- ❖ 2-3 weeks to design, build, and test
- ❖ Test results
 - ❖ Could sense error symbol in all light levels
 - ❖ Difficulty with reflected light
 - ❖ Obstructed view of display



Technology Feasibility - V2

- ❖ Pivot and design change
- ❖ Camera chip sends image of LCD display
 - ❖ Easier to handle reflected light
- ❖ Transmit entire image
 - ❖ Heavily compressed image
 - ❖ Large amount of data still makes detection easier
- ❖ Technical challenges
 - ❖ Reflected light / proper illumination
 - ❖ Transmit entire image with low power consumption
 - ❖ What type of wireless transmission?



Mechanical Feasibility: V1 vs. V2

LED Method



Camera Method



VS



Technology Feasibility - V2

- ❖ Built and tested mock-up (2 – 3 weeks)
 - ❖ Built circuit from development boards (off the shelf)
 - ❖ Mechanical fixturing (board and light mount/shroud)
- ❖ Test results
 - ❖ Detection worked in all light conditions
 - ❖ Display obstruction satisfactory
 - ❖ Determined housing could support solution
- ❖ Cellular service met requirements best
 - ❖ Available where AEDs are located
 - ❖ Simple installation, no repeaters required
 - ❖ Low monthly cost



Technology Feasibility V2

Integrated Camera System



Product Feasibility Conclusions

- ❖ Regulatory impact
 - ❖ Knew what regulatory path was required
 - ❖ Lower cost and lower risk
- ❖ Impact of feasibility technical work
 - ❖ Avoided designing a product that didn't work
 - ❖ Saved two months and 10% of Dev. Cost
 - ❖ Lowered project risk – remainder of project had little uncertainty
- ❖ Product Requirements Document complete
- ❖ Design schedule and cost accurately estimated
- ❖ Ready to begin the design



Feasibility Tips (summary): Q&A

- ❖ Identify risks early (regulatory, technology, manufacturing, etc.)
- ❖ Evaluate multiple solutions
- ❖ Use known & easily available technology
- ❖ Consider emerging technologies & markets
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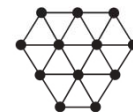
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