“USER NEEDS DRIVE PRODUCT DEVELOPMENT IN MEDICAL DEVICES”

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LISA SASSO, MBA, CPCC, ACC

- As an Executive Coach, Lisa empowers aspiring leaders and executives in the medical device and life science fields to achieve personal and professional goals with balance and gratitude.

- As an entrepreneur, Lisa experienced the challenges of working on novel medical devices. She demonstrated her leadership skills as co-founder of Radi Medical Systems, Inc., a high-tech medical device company specializing in innovative cardiology products (wholly owned subsidiary of a multinational firm). During her six-year tenure as president/CEO, she grew the company from inception to revenues of $28M with profitability. Lisa was recognized and ranked #28 out of 100 Women Led Businesses in Massachusetts in 2004.

- Lisa is an inspiring motivational speaker and author who has delighted audiences including entrepreneurs, business leaders, professionals, working mothers, people in transition, and students. Lisa earned a BBA in marketing and a BA in economics, from the University of Massachusetts; and an MBA from Bentley University, graduating with High Distinction.
• Executive Coaching for Medical Device Professionals
• Grow your Company & Yourself to Reach Your Potential
• Certified Professional Coach, MBA, CPCC, ACC
• Motivational Speaker & Partner to Med Dev Executives
• Executive Experience – former CEO Radi Medical Systems, Inc.

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RADI MEDICAL SYSTEMS, INC. PRESSUREWIRE ®

• Used in both Diagnostic & Therapeutic Procedures

• A pressure wire is a device that can be used during coronary procedure to determine if a narrowing (stenosis) in one of your heart arteries (coronary arteries) requires further treatment. A pressure wire enables measurement of the pressure difference across a stenosis to determine if the stenosis causes a significant reduction in blood flow to the heart muscle (i.e., a Fractional Flow Reserve (FFR) measurement).
Two types of coronary wire systems used in “procedures”
- Rapid Exchange (RE) – requires 175cm length wire
- Over the Wire (OTW) – requires 300cm length wire

175cm PressureWire introduced in Europe – majority use RE

U.S. Market split more evenly between RE and OTW use

U.S. Market Launch with 175cm wire missed market share

Required Effort: Collect evidence and work with Product Development to overcome challenges with longer wire (signal quality)

Grew sales by 33% with this one line extension
UNDERSTANDING USER NEEDS

• User needs are critical to the design process – They **Drive** it!

• They form the basis for your “design inputs” (Product Requirements)

• Capturing User Needs is difficult, your customers (doctor’s) don’t always know their needs

• Requires problem solving approach and careful observation

• Consider the constraints of existing procedures (how might they limit the solution)

• Don’t be afraid to think outside of the box; **consider what a different procedure might look like**, or perhaps a procedure done in a different setting by a different set of clinicians.
USER NEEDS: A LIFE LONG PROCESS (1 OF 2)

- Sometimes the initial product you develop (for a certain intended use) may end up being used for something different

- **Ex/ Bard’s FemoStop Compression System**
  - Used to achieve hemostasis of a groin puncture after angioplasty
  - Also used for Pseudoaneurysm repair - 95% effective
  - Regulatory filing to expand intended uses (w/Study data)
  - Performed after the initial launch; expanding the market all because of stakeholders feedback

- **Caution**
  - Be aware of regulations regarding off label use.
  - Can’t promote it.
USER NEEDS: A LIFE LONG PROCESS (2 OF 2)

• 5 PressureWire® versions released over the course of 5 years.

• All based on user needs for improved features  Listening to the Voice of the Customer (VOC).
  • Better torque
  • Better handling
  • Better maneuverability
  • Interface to RadiAnalyzer® (Capital Equipment improvement)
BUSINESS MODEL (RAZOR-RAZOR BLADE)

- Product Development plays a key role in how a product will be sold.
  - Disposable vs. Capital Equipment (Reusable costs)
- Radi- PressureWire®-consumables
  - Guidewire and Analyzer
  - Buy guidewire, lease/rent Analyzer
  - (Various programs) – Segmentation to buy outright
“REGULATORY” VS “REIMBURSEMENT”

• Users require products that are cleared by regulatory authorities and reimbursed by the healthcare system in which it is sold.

• Drive the **regulatory** approach: the higher the product risk, the more complex the regulatory path and submission requirements
  - **US**: FDA regulations govern product clearances/approvals (510(k), de Novo, PMA)
  - **Europe**: Medical Device Directive (Medical Device Regulation) govern CE Marking requirements

• Product development has to support the case for **reimbursement** (example PW)
  - Presented data to CMS (Center for Medicare/Medicaid Services) for improved coverage decision.
FINAL TAKE-AWAYS

• Build the right product based on what doctors, customers, healthcare providers, hospital’s (stakeholder) needs are. Ex./300cm wire

• Keep your stakeholder needs at the forefront through the product development.

• It is a life long process in terms of achieving user needs.
  • Listen to the Voice of the Customer
  • User Needs change over time especially as they gain experience with your product
THANK YOU!

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