

BUSINESS SUCCESS Case Study

Global Medical Device Company Strategic Turnaround Management

PENTAX MEDICAL FACTS

\$60mm leader in endoscopy medical devices.

Project Timing

Six months turnaround management program.

Project Results

One year to realize results.



*Thought Leadership Management Forum
Lessons Learned*

SUCCESS STORY

Problem: To realign organization with corporate “pull” strategy through valuation of antiquated software solution to lead medical device division into deeper opportunities globally. To create best of breed endo-imaging total solution (image/data capture, storage and search) through redesign and development and in compliance with global regulatory compliance.

Action: Developed plan by separating business unit from core medical device business by rebranding division. Realigned R&D engineering, field service, and sales. Executed and conducted a UX needs and satisfaction study with key leaders at pedigree medical institutions. Oversaw team. Worked closely by directing software engineering, product direction, and business plan for global launch.

Result: Successfully lead turnaround management direction, Go-to-Market, and commercialization plans. Total solution is compliant with new laws as it maintains changing pace with healthcare sector: HL7, HIPAA security, FDA regulations, user experience, interoperability and big data analytics. Created scalable version for decentralized resellers in APAC and EMEA for easy load/easy use solution. Expanded market value through scalable platform as clinical/technical demands evolve. Awarded DIACAP certification through focused efforts. Revenue growth immediately realized via VA and DoD. Architect for 5 year pro forma and technical roadmap with multiples of 10X growth expectations from initial investments. Pull strategy in full affect leading medical device team into new growth opportunities within an oversaturated market.

TESTIMONIALS

President, PENTAX Medical, Americas

“PENTAX Medical is committed to introducing both software and hardware innovations that enhance quality, boost efficiency and improve data management and security. The innovative features found in the endoPRO iQ 7.6 deliver on these important goals.” David Woods, EVP, WW Marketing, Pentax Global, (formerly) President of PENTAX Medical, Americas.

PENTAX Medical, Global Director of Engineering

“The enormous mountain of work to tackle in a short period of time; amalgamating the various sources of truth of our install base to our future roadmap for the franchise, Jeanmarie was able to engage, lead and produce results. The roadmap that HTS developed, including its breadth of information, vision and level of detail, was the best our franchise had ever seen. The output was very strong and realistic. Jeanmarie Tenuto was not only a pleasure to work with but also a source of inspiration.” David Narine.

THE CUSTOMER

Pentax Medical is a division of Hoya Group delivering endo-imaging solutions. Established in 1919 and headquartered in Japan, Pentax Medical has a worldwide focus and presence with R&D, regional sales, service, and in-country facilities around the globe. In Japan, Pentax Medical is a globally diversified company with R&D and manufacturing in Japan, Europe, and USA. The mission of Pentax Medical is to improve the standard of patient care and quality of healthcare delivery.

THE CHALLENGE

In an oversaturated marketplace, the endoscopic medical arena is dominated by a few companies. Differentiation among products is slight and is mostly driven by perception of brand and deepened by ease of use. Pentax Medical's endoPRO iQ® image and data capture software solution was an antiquated system. However, it was built as an interoperable system compatible with any brand of endoscopic medical device. The software had been in the market over a decade. Many versions had been deployed and the lifecycle process needed oversight.

The US Healthcare sector has been moving fast with its new era of digital technology. While holding its market steady, Pentax Medical realized corporate growth opportunities in its software solution. The variety of versions in the marketplace created the need to have stronger monitoring and business control mechanisms. Further, the current software process required more introspection into the product itself to keep current in this ever-changing environment of healthcare delivery. As a strategic initiative, the software presented a growth opportunity to the company, with a turnaround management plan.

The ideation was accepted by management; however, the journey would be a challenge. "Change" typically is faced with ever-increasing pressures during the phases where internal stakeholder buy-in and market pressures may prevent critical pivotal shifts including:

- ◆ Time pressure
- ◆ Regulatory pressure
- ◆ Customer pressure
- ◆ Internal morale / credibility
- ◆ Stakeholder pressure
- ◆ Competitive pressure and advantages
- ◆ Differentiation in oversaturated, me-to market
- ◆ Fledging software
- ◆ Competitive technical disadvantages

THE SOLUTION

Jeanmarie Tenuto, was brought into Pentax Medical to direct the global turnaround management program for endoPRO iQ. To manage the effort and execution of this portfolio required experience, knowledge, and the business attention to harmonize efforts and ultimately produce best of breed products.

TURNAROUND EXECUTION

The turnaround execution development plan was deep rooted in research and analysis. It was imperative the software solution maintain its autonomy from the core business. After separating the product from the core business, a realignment of R&D engineering, field service, and sales was put into effect. Focus groups were conducted for user experience, needs, and satisfaction study. A more thorough analysis was executed with key leaders at pedigree medical institutions and later beta sites.

While overseeing and closely working with the software engineering, implementation, field services, and sales teams, in-depth secondary market research and education was conducted including: Global health trends analysis for planning and development; Pricing structure and new laws related to medical device taxation in US and abroad; Global regulatory protection environment for I.P. (patents, copyrights and trademarks); and Global regulatory process for Medical Software and Medical Device usage (FDA, HIPPA, Sunshine Act).

A stringent and detailed project management plan was casted for agile software development. Agile project management methods swiftly moved the product through the Verification and Validation process assuring the software system would meet outlined specifications and fulfill its intended purpose.

THE RESULTS

Within one year the turnaround management program commenced, PENTAX Medical announced the U.S. and Canada launch of the new endoPRO iQ® 7.6, the company's newest version of its information technology (IT) and image management software for endoscopy units. The new software promotes industry best practices for endoscopic documentation, reporting and analysis of quality, efficiency, and equipment utilization data.

In leading this successful turnaround management initiative, the software solution is now fully compliant with new laws and maintaining pace with changing healthcare industry. The new software version is up to code with HL7 for interoperability, HIPAA security, FDA regulations, while its user experience and satisfaction has improved beyond expectations. As the channel partners in APAC and EMEA are decentralized, the software solution is now updated for global launch offering those resellers a product that is easy to load / easy to use, scalable solution. To realize revenue growth immediately inside the VA and DoD, the software was awarded DIACAP certification through a concentrated effort and cooperation with the US Government. This would later become an unique competitive advantage for serving military operations globally.

For the organization, architected of 5 year pro forma and technical roadmap with multiples of 10 times growth are expected from the initial investments. The solution has expanded market value for the company by designing a scalable platform to meet the ever evolving technical and clinical demands.