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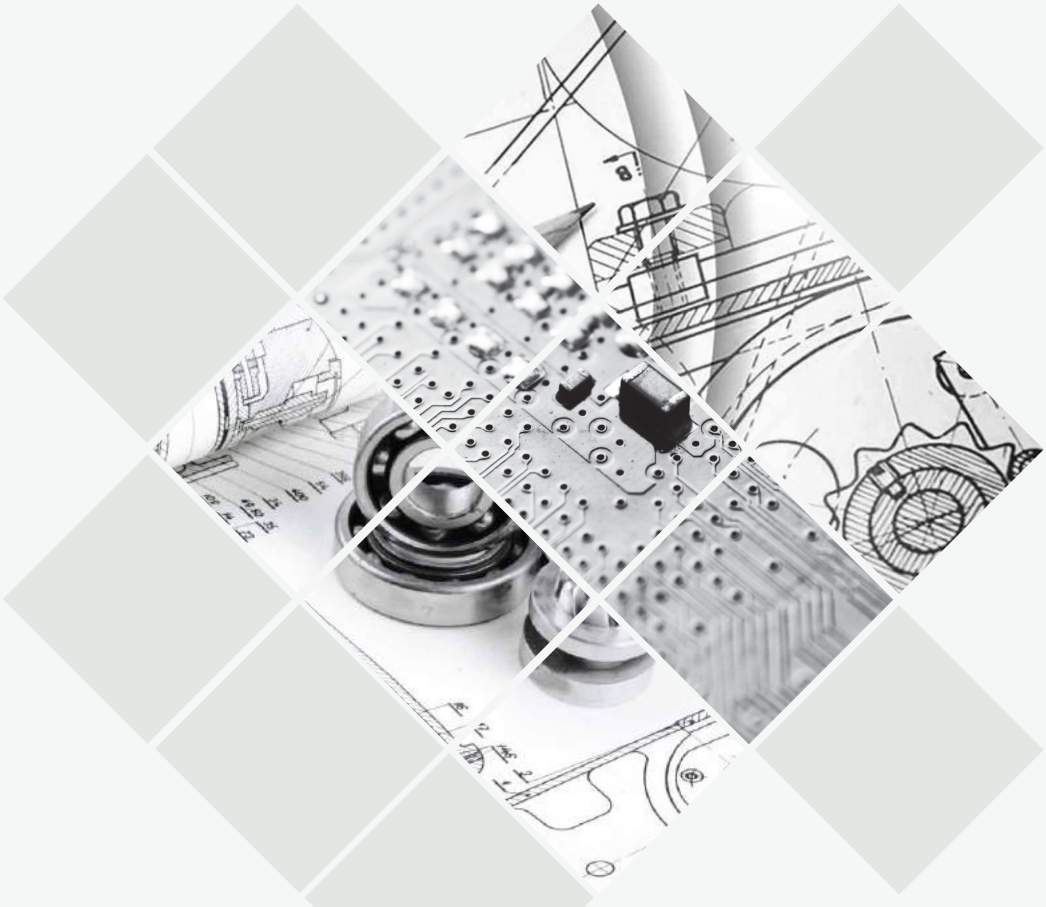
strategic engineering R&D outsourcing in medical devices industry



Bindu Annie George & Sajitha A H
Principal Architect, Medical Devices
QuEST Global

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Abstract

R&D outsourcing often leads to enhanced effectiveness by permitting companies to focus on core competencies and reduce involvement in non-core activities. Outsourcing enables Medical Devices OEMs to maximize innovation, reduce costs and thereby improve overall company performance.

This paper elaborates on how Medical Devices OEMs can leverage R&D outsourcing as an effective solution to become global players in the market.

1. Background

According to a news release on PR Newswire, "The medical device market is one of the fastest growing and the most dynamic sector in the life sciences industry due to its high profit margins and the increasing demand for advanced medical devices."

For a product company in any industry, success of a product in market lies in giving the end users an out of the world feeling (a wow factor). To achieve this goal, considerable investment like identifying end user problems, their expectations and coming out with innovative and viable solutions are needed. Healthcare industry is seeing extensive growth with governments and private agencies setting their prime priority as providing good healthcare to people. The scope of research and development in the field of medical devices industry is enormous. Many players are in the foray and competition is thriving among the medical devices companies to deliver the best products to market using the full potential of latest technology advancements.

This white paper elaborates how medical devices companies can leverage R&D outsourcing as an effective solution to become global players in the market.

2. R&D Outsourcing in Medical Devices Industry

A market report highlights that "the global medical devices outsourcing market, amidst ongoing medical technology development is expected to rise from USD 21.1 billion in 2012 to USD 40.8 billion in 2018, registering a CAGR of 11.6% from 2012 to 2018." Outsourcing is gaining significant importance among OEMs (original equipment manufacturers) as it helps to leverage their scarce resources and maximize core competencies.

FDA classifies medical devices based on the risks associated with the device. Devices are classified into one of three categories: Class I, Class II, and Class III – Class I being of lowest risks and Class III of highest risks. Developing software for medical devices that comply with FDA's Quality System regulation is very challenging. Medical devices OEMs typically consider outsourcing software development of Class I and Class II devices while Class III development is handled by the OEMs themselves.

Need for Outsourcing

With competition abound in the medical devices industry, following are the key triggers for outsourcing by medical devices OEMs

- **Periodic releases of newer product versions for faster market entry**

Typically, medical devices OEMs launch new products to market every 5 or 10 years. In between the major product launches, numerous version upgrades of existing product lines are required. End users are always on the lookout of upgraded products with improved usability and more innovative features. Companies face stiff competition as each one tries to capture the maximum customer base.

- **Manage budget allocation swings**

Annual budget planning of medical devices companies generally come out with varying budget allocation for software and hardware development - primarily dependent on company strategy and economic situation. During downturns, companies face software R&D budget cuts and are forced to close projects which in turn requires releasing core resources. The reverse happens during upswings when the R&D budget is increased but there is increased challenge in getting the required number of rightly skilled technical resources from the market.

- **Switch to newer technologies**

With technology advancing in leaps and bounds and competition intense, all major product companies are strategically required to keep pace with advancements and release new products to market. For example, medical devices companies are now exploring the options of adopting SMAC technologies for better user connectivity and experience. This require companies to reskill their engineers or recruit new talents in the niche areas. In the long run these are not effective solutions which can have severe cost impact.

- **More Focus on market analysis and market conditions**

Product development is an intense and time consuming activity which require lot of attention. If the medical devices OEMs' technical resources are locked in the nitty gritty of product development, they will be devoid of time to study the market conditions, perform market analysis and come out with innovative ideas and end user requirements. As a matter of fact, these are the activities of high priority considering market impact.

Challenges involved in Outsourcing

Medical devices OEMs face the following challenges while identifying suitable outsourcing providers.

- **Regulatory and medical standards compliance**

Patient safety is very critical for medical devices and the entire development process (software and hardware) goes through stringent quality checks. The medical devices are required to be certified by agencies like FDA, EMA before market launch. Outsourcing providers are required to have the necessary certifications and standards in place if they have to participate in the development process.

- **Information security and protection of IPs**

Medical devices companies are generally reluctant to make available their data in facilities outside their premises in fear of information security breach and protection of their intellectual property rights. Outsourcing providers need to have proper infrastructure in place which ensure that there will be no data leakage of customer artefacts.

- **Accountability**

Maintaining healthy relation based on trust and integrity with the outsourcing provider is very essential for the success of outsourcing. An open and transparent environment with

contractual agreement need to be made available.

Areas of Outsourcing

Activities in the product development lifecycle can be segregated into core and non-core activities. Outsourcing non-core activities have direct impact on saving energy and time of core technical resources of medical devices companies and redirecting their effort to more value added activities.

The following figure (*Figure 1*) shows the typical activities associated with medical software development lifecycle. As depicted in the figure, many activities can be identified as non-core and considered for outsourcing. Companies need to analyze their development cycle, identify areas that can be outsourced, weigh the benefits, identify suitable outsourcing providers and proceed.

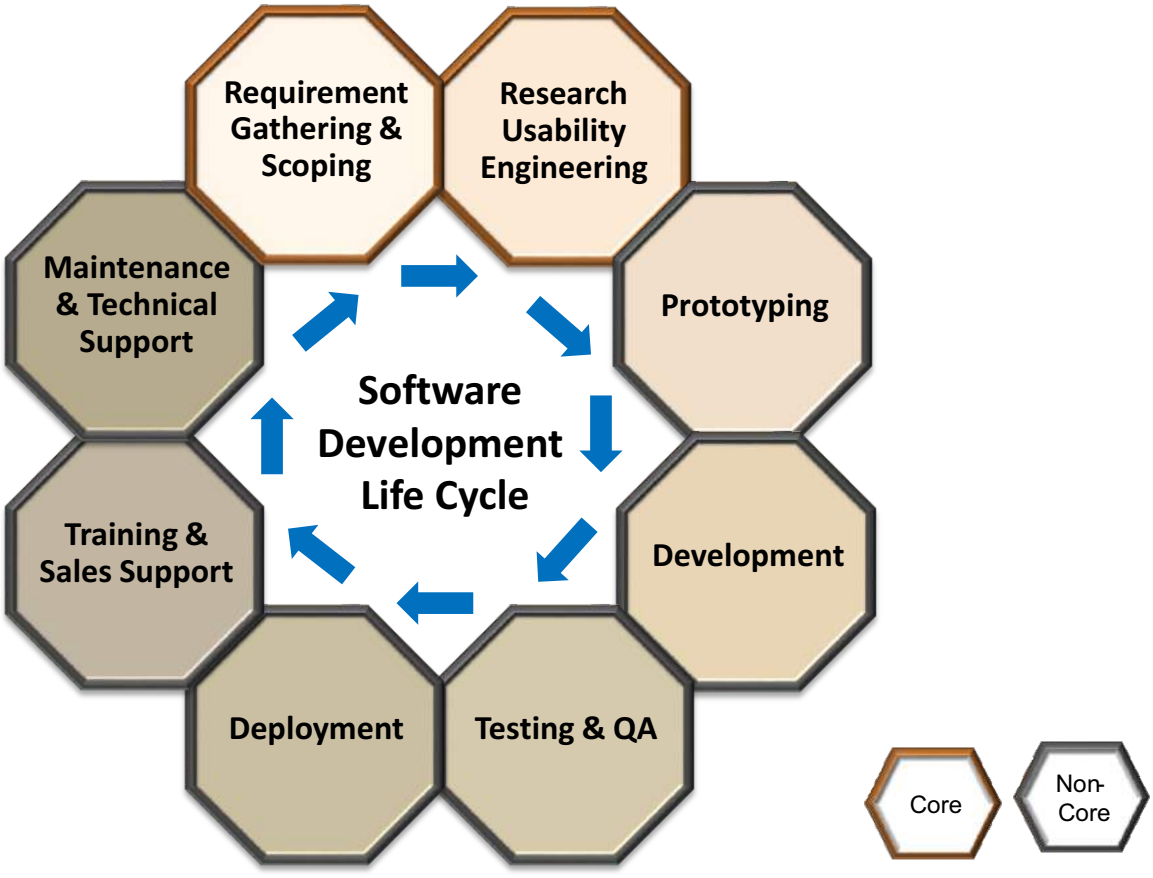


Figure 1: Software Development Lifecycle

Three key drivers for R&D outsourcing are:

- Quick prototyping for faster market feedback
- Sustenance service of multiple product lines
- Product upgrades in sync with technology advancements

Quick prototyping for faster market feedback

It is highly important that medical devices OEMs understand the pulse of their market and deliver as per customer expectations. Collecting

feedback after the completion of the product development is not often prudent with adverse impact in case of major design changes and product rework. Adopt the strategy of developing small prototypes, conducting end user evaluation and collecting feedback – proceed with development of features that have user acceptance. This strategy ensures that only features which provide value addition to the end users are included in the final product.

The success of this model lies on how fast the prototypes are developed, successfully evaluated and included in the product without impacting the overall product release milestone. Outsourcing is an optimal solution to implement this model and medical devices OEMs can concentrate on end user evaluation, collecting market feedback and new requirement scoping.

Sustenance service of multiple product lines

With multiple products (including legacy systems) in use across the healthcare space, medical devices OEMs find it challenging to provide quick and efficient sustenance service. Minimal SLAs for market issues is of prime importance for a company to retain the market dominance. Providing in-house L2 & L3 support of legacy software will drain time and effort of the core technical resources of these OEMs.

The following challenges can be addressed if sustenance services are outsourced

- Core technical team held up in sustenance services
- High maintenance cost of legacy software
- Frequent software upgrade and launch requirements
- Multi-platform support
- Configuration management for multiple models and versions
- Continuous end user support (24x7 support)

Product upgrades in sync with technology advancements

In this modern age of smart devices, customers' expectations are sky rocketing. Medical devices, rather from the traditional way of usage, are seeing a major shift in the way users get to operate the devices. The medical devices companies are required to have sufficient resources skilled in the latest technologies which is generally not the case. Outsourcing provide the companies with multiple options to identify best suited outsourcing providers with required skillset and release products running on latest technology at faster rate.

Benefits of Outsourcing

Key advantages of R&D outsourcing are :

- Shorter time-to-market
- Focus on core activities
- Availability of vast talent pool
- Access to state-of-the-art technologies
- Better operational control

3. QuEST Solution

With over 15 years and 3000+ person years of work experience in the medical domain, QuEST has focus, skills, technical expertise, infrastructure, tools, solution frameworks, processes and methodologies to execute product engineering services. QuEST has devised practices and processes to address the key drivers in engineering software outsourcing in the medical devices industry.

Regulatory and Medical Standards Compliance

QuEST QMS satisfies the requirements of regulatory compliance in the medical domain. QuEST being an ISO 13485:2003 (QMS for medical devices) certified company and having IEC62304 compliant development process, all medical software development projects follow the processes and guidelines specified by ISO 13485/IEC62304. Regular audits are conducted at project and organization level for compliance verification.

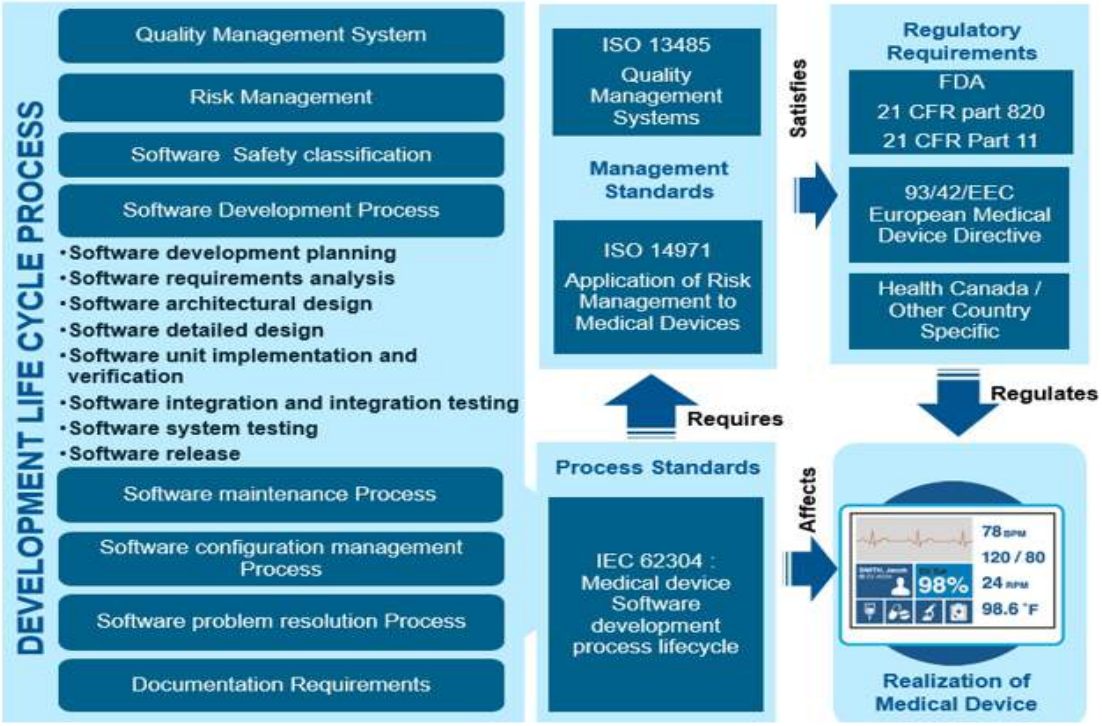


Figure 2: Regulatory and Medical Standards Compliance in Software

Information Security & IP Protection

QuEST is an ISO27001 certified company with a strong Information Security Management System (ISMS) in line with the defined risk assessment criteria, meeting all business, legal and statutory requirements applicable to the organization. QuEST ensures the confidentiality, integrity and availability of data in all forms.

IP protection is ensured by:
1. Non-disclosure agreement with the vendors
2. Employee confidentiality contract

Two models adopted by QuEST as IP management strategy:

1. Offshore Development Center (ODC)
2. Shared Infrastructure Model

The ODC Model offers the highest level of security and isolation. The ODC functions both physically and logically independent of QuEST's network, which in effect would be a logical extension of the customer's network. It involves installation of exclusive servers and network equipment. This model proves to be a high-cost model.

The Shared Infrastructure Model makes use of QuEST's IT infrastructure. This includes the Internet link, network setup, servers, services

(fileserver, printer etc) and the LAN. Adequate security measures are implemented at each level to provide data and network security. Engagements are typically provided a physically separate work area with restricted access. LAN is segregated by VLAN to isolate and segregate network traffic.

Quick Prototyping

QuEST is having vast pool of technical resources with extensive medical domain expertise capable of supporting quick prototyping model for fast realization of market requirements of medical devices OEMs. This model helps the OEMs to have market/ end user evaluation of requirement very quickly and decide on the requirements priority based on market pulse.

Typical process followed for quick prototyping is depicted in the following figure. (*Figure 3*)

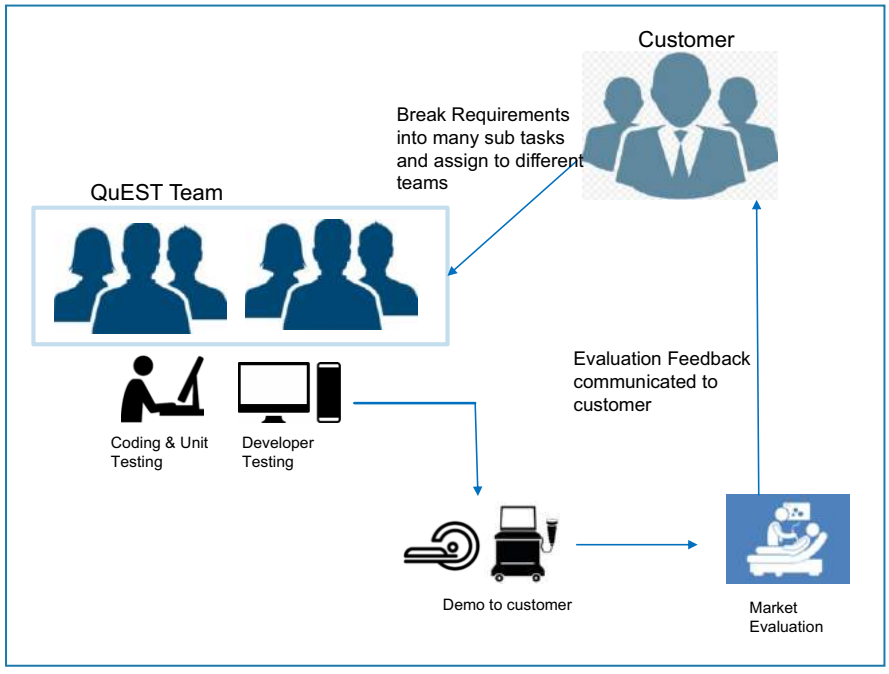


Figure 3: Quick Prototyping Model

The advantages of quick prototyping model are

- Evaluation possible for individual features
- Quicker feedback from market
- Incorporate only what the end user wants
- Avoid wastage of development time

Sustenance Services

QuEST provides a defined solution for product sustenance management. Software sustenance offerings include

- Software Maintenance (Bug Fix, Patches, Migrations)
  - For legacy and new generation systems to suit various customer requirements and to be at par with market trends
- Software Optimization Solutions
  - Engineers with in-depth domain and software expertise provide solutions that can optimize the product and take it to higher levels

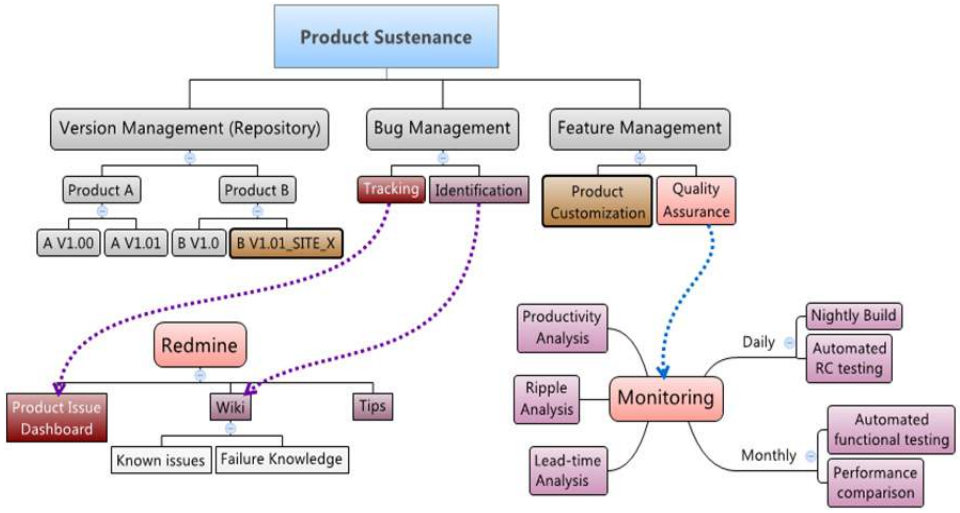


Figure 4: Sustenance Management Model

- Product Testing Solutions
  - Manual or Automated Testing of engineering software applications on generic platforms such as PC, Web, Mobile, Cloud and Embedded Systems
- Build & Release Management Solutions
  - Support product release for software systems powered by our continuous integration management framework

Sustenance management followed at QuEST is sketched in the above figure. (*Figure 4*)

Technology Adaptation

Technology Excellence Group (TEG), group within QuEST responsible for managing co-creation of IP and innovation support to our customers, continuously evaluates the emerging technologies and its applicability to specific domain or requirements and generate guidelines to adopt the technologies. TEG finalizes the pertinent technology for a market requirement and develop in house competency. This enables QuEST to maintain a pool of

Figure 5: Technology Stack

engineers skilled in these advance technologies. Whenever customer queries are received, QuEST is well prepared and can place the best suited engineers for the new tasks.

Best Practices

QuEST has adopted the following best practices for providing efficient R&D service to medical devices OEMs.

- Well defined QMS with certifications
  - CMMI-DEV v1.3
  - ISO 13485
  - ISO 9001:2000
  - ISO 27001
- Well defined and documented MSA
- Defined reporting and communication charter
- Product risk analysis (FMEA)
- Knowledge sharing across modality development teams
- Statistical approach for effective test design
- Mind mapping tools for requirement analysis and test design
- Continuous monitoring and analysis of defined KPIs
- Implement cost saving initiatives

4. Case Study

Extended R&D Centre for complete software product portfolio management with a Medical Devices OEM *(Figure 6 & 7)*

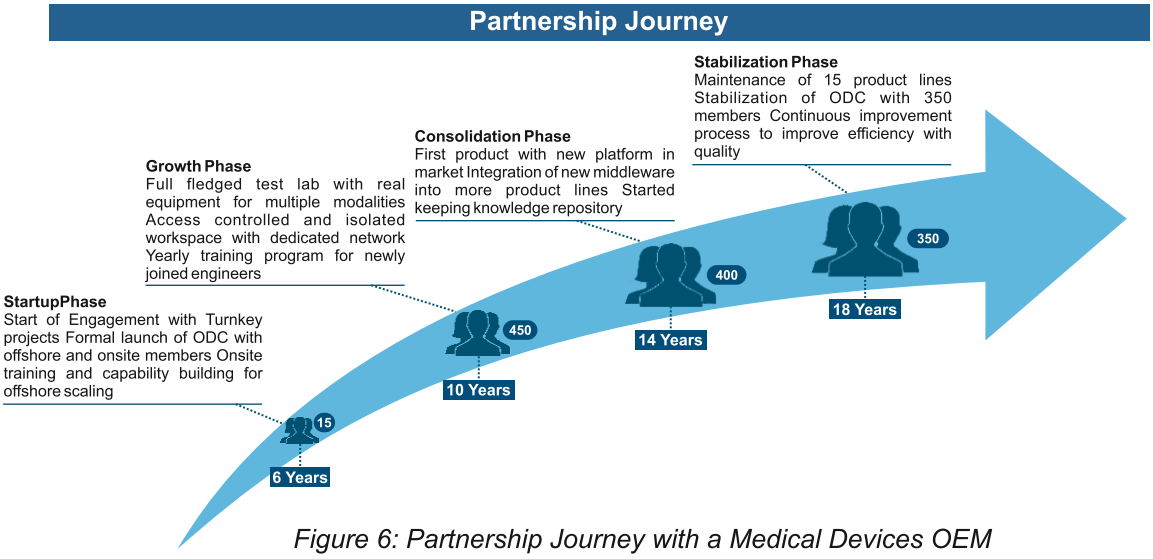


Figure 6: Partnership Journey with a Medical Devices OEM

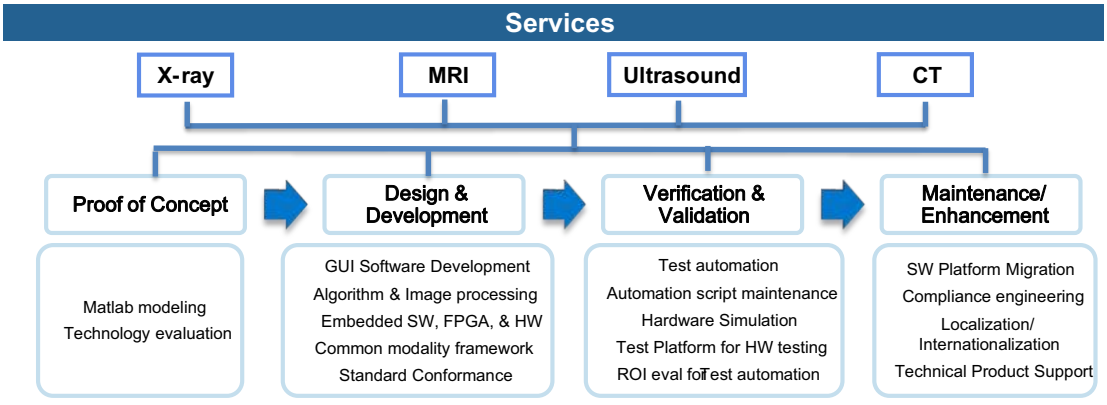


Figure 7: R&D Engagement

Highlights

- Software **engineering and sustenance partner** and an extended R&D arm for medical imaging
- **15-year-long association:** From just another supplier to a strategic partner
- **Continuous improvement** in defined **KPIs** and **cost efficiency**
- Supports IHE Connectathon, RSNA etc.
- Quarterly review with senior managers of the medical devices OEM

5. Conclusion

Medical devices OEMs can choose outsourcing to reduce costs, minimize business risks and faster time to market of their products. Outsourcing often leads to enhanced effectiveness by permitting the company to focus on core competencies and reduce involvement in non-core activities which can very well be supported by outsourcing providers. Successful implementation of outsourcing will prove advantageous to these companies by maximizing innovation and thereby improving overall company performance.

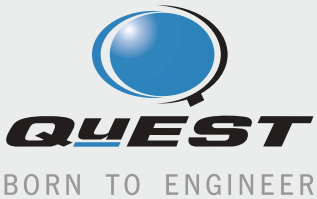
Author Profile

Bindu Annie George

Bindu Annie George is a Principal Architect in the Medical Devices BU of QuEST Global and is based out of Trivandrum. She joined this company as a fresh campus recruit and has completed 20 years. She has worked on projects in Broadband Communication and Healthcare domain. For 12 years, she has worked in the ultrasound modality leading large teams contributing in the release of multiple ultrasound product lines to market for a leading Medical Devices OEM. Currently, she is working on New Business Development initiatives in Medical Devices BU. She holds a Bachelor degree in Computer Science & Engineering.

Sajitha A H

Sajitha A H is a Principal Architect in the Medical Devices BU of QuEST Global. She has more than 20 years of experience in software industry. She has worked on projects in Broadband Communication and Healthcare domain. For past 13 years, she has been working in healthcare domain for a leading Medical Devices OEM in Japan. In her long tenure in QuEST, she could handle multiple roles ranging from technical lead to delivery manager handling different types of projects. She holds a Bachelor degree in Electronics & Communication Engineering.



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