



Experience that Matters....

Market Accelerator™ Program Overview

Product development is challenging. All-too-often the challenge is not in development of technology or engineering, but in setting the course for the project correctly. Quest's Market Accelerator™ program is focused on charting this course through two activities:

- 1) Up-front documentation: This documentation includes:
 - a. Product Requirements Document (PRD)
 - b. Initial Risk Analysis (IRA)
 - c. System Architecture (SA)

High-value versions of these documents are critical to program success. Poorly conceived documents represent the Achilles-heel to a successful program.

- 2) Mitigating technical risks: Mitigating risks ensures the effective execution of a schedule against a budget. Resolving the “unknown” allows the team to proceed in a successful and predictable manner.

Quest's Market Accelerator™ program will reduce risk through the above activities!

The importance of a clear set of requirements in the form of a PRD and IRA cannot be over emphasized. The content of these documents provides the basis for the System Architecture (SA), subsequent design activities, and all verification and validation activities. The PRD and IHA also represent the basis for the technical content in a regulatory submission or a technical file for international ISO certification.

Quest's Market Accelerator™ Program provides the structure and methods for the creation of these documents. The program empowers our clients to accelerate the development of their product while meeting user and FDA requirements by leveraging the 20+ years of Quest's experience. The Market Accelerator™ program establishes a team that lives throughout the life of the program. This team consists of subject matter experts from the client, Quest, and possibly end users.

Specific Activities

There is much more to the program than the simple creation of documents. The program begins with a kickoff workshop for 1-2 days. During the beginning of the workshop it is expected that the client will present their expectations for the product including:

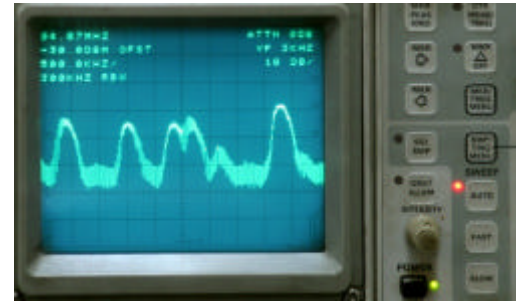
- Overview of the product
- Similar competitive products
 - ♦ Market size
- Target customer
 - ♦ User needs
 - ♦ User profile
 - Target education level
 - Physical considerations
 - ♦ Target patient
 - Adult
 - Pediatric
 - Geriatric
- Anticipated distribution volumes
- Target countries
- Cost goals



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All of the above information may not be known. To the degree that it is known, it should be presented. Information that is not known represents potential points of risk and should be addressed quickly.

After introduction to the product, the discussion will be lead by Quest to draw information from the client for the creation of the documentation. It is often the case that there are areas where technical, market or competitive research needs to be conducted. Further research might include understanding of guidance documents and consensus standards that apply to the product.



Product Requirements Document (PRD)

The PRD characterizes the desired performance characteristics as well as all other requirements of the device like physical characteristics, immunity to shock and vibration, specific regulatory requirements, electrical safety testing and countries of distribution. The countries of distribution will further define regulatory and compliance requirements. Care must be taken during the development of the PRD in that any requirement that is defined becomes the root of all verification activities.

Initial Risk Analysis (IRA)

The Initial Risk Analysis (IRA) is based on the PRD outlining risks of the device in any form to the patient and personnel that might administer treatment with the device. At this phase of the development effort, the mitigations for each risk are viewed as fundamental requirements. The risk analysis process consists of identification of basic risks that the device may possess and how those risks can be minimized with appropriate engineering or scientific steps.

System Architecture (SA)

The PRD and IHA will be utilized to form a System Architecture. Often there is strong interactive activity between the client and Quest in the architecture formulation to identify key elements within each of the disciplines, electrical, mechanical and software engineering. It is common that a single requirement impacts more than one discipline. It is the purpose of the System Architecture and documentation to lay the foundation and accelerate all subsequent design work through clear definition of architectural elements. Each architectural elements is associated with requirements in the PRD and IRA to ensure that all are appropriately addressed.

Mitigation of Technical Risks

During the evolution of the above documents and system architecture there will be areas where complete solutions are not known. The question "Can that be done?" will be asked. It is important to be sure that technical risks like these are addressed before full development begins. Quest will identify these areas and define small research efforts to demonstrate feasibility for solutions to technical risks. These research efforts will be executed by Quest or the client to ensure the success of the program.

