



Experience that Matters....

Quest's Market Accelerator™ Program

Product development is challenging. All too often the challenge is not in the development of a 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:
 - a. Product Requirements Document (PRD)
 - b. Initial Risk Analysis (IRA)
 - c. System Architecture (SA)

One of the most common sources of program failure is found in poor up-front documentation. Accurate, complete and timely documentation is critical to the success of a product development program.

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

Quest's Market Accelerator™ program will reduce risk through these activities

The importance of a clearly defined set of requirements in the form of a PRD and IRA cannot be over emphasized. These documents provide 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 certification.

Quest's Market Accelerator™ Program facilitates complete project documentation, and 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 dedicated team for the life of the project consisting of subject matter experts from the client, Quest, and often end users.

Specific Activities

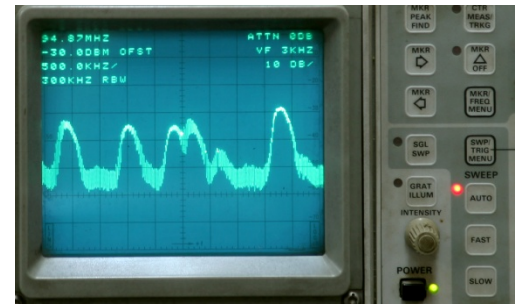
The program is much more than the simple creation of documents; it is an interactive process encompassing all aspects of design and development. The program begins with a one or two-day kickoff workshop. The client initiates the workshop by presenting their expectations for the product, including:

- Overview of the product
- Similar competitive products
 - ♦ Market size/cost goals
- Target customer
 - ♦ User needs
 - ♦ User profile
 - Target education level
 - Physical considerations
 - ♦ Target patient
 - Adult, pediatric, geriatric
- Anticipated distribution volumes
- Target countries



1) Up-Front Documentation

After the introduction to the product, the discussion will be lead by Quest to draw out additional information from the client in order to create complete 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. All unknown factors (requirements, expectations, etc.) should be identified and researched as quickly as possible.



- **Product Requirements Document (PRD)**

The PRD identifies the desired performance characteristics as well as all other requirements of the device, for example physical characteristics, immunity to shock and vibration, specific regulatory requirements, electrical safety testing and countries of distribution, to name a few. 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 and outlines the risks which the device may pose, in any form, to the patient or personnel who might administer treatment using 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 identifying basic risks that the device may pose and how those risks can be mitigated with appropriate engineering or scientific steps.

- **System Architecture (SA)**

The PRD and IRA are used to form a System Architecture. Regular and thorough communication between the client and Quest is important in formulating the architecture in order to identify key elements within each of the disciplines-electrical, mechanical and software engineering. Often, a single requirement impacts more than one discipline. The purpose of the System Architecture and related documentation is to lay the foundation and accelerate all subsequent design work through a clear definition of architectural elements. Each architectural elements is associated with requirements in the PRD and IRA to ensure that all are appropriately addressed.

2) Mitigation of Technical Risks

During the Market Accelerator™ program, there will be times when problems are identified and solutions are needed. Questions will be asked like “Can that be done?” or “How will we do that?” It is important to ensure that all known technical risks are addressed before full development begins. Quest will identify these risks and define feasible research efforts to solve them. These feasibility efforts may be conducted by Quest the client, or jointly.

Summary

As a contract product development and manufacturing firm, Quest interacts with many clients. Poor up-front documentation is one of the most common occurring challenges that Quest encounters and it is very common in the medical device industry including fortune 500 organizations. The Market Accelerator™ program was created at Quest to reduce the risk of program cost over-runs, schedule slip of feature creep through the creation of this vital documentation.