Product Requirements for Non-medical Devices

The development of an any product, begins by defining the market. A company believes that they have an idea for a product that will solve a particular problem. The first step is to create the **Marketing Requirements Document** (MRD) written from the point of view of the customer.

The purpose of the **Product Requirements Document** (PRD) or product specification is to clearly and unambiguously articulate the product's purpose, features, functionality, and behavior for the development team. Careful writing of the requirements can aid in a more rapid approval process.

When writing the PRD and System requirements, each requirement should be testable and measurable. For example, rather than having a requirement "The system will inflate a balloon.", a measurable requirement would be: The flow rate from the system will inflate the balloon to 4 psi in four seconds.

Marketing Requirements Document (MRD)

This is an overview of Market Need, usually from the marketing perspective. It covers these things:

Market Need
At an overview level
why is your product needed?

Target User
Who will use your product?

Target Purchaser
Who will buy your product?

When writing the PRD each requirement should be testable and measurable.

Product Requirements Document (PRD)

The PRD should clearly specify all product level requirements including:

- Functionality
- Usability
- User Interface
- System Interface
- Environmental
- Manufacturing
- Serviceability and Support

- Alarm and Annunciators
- Performance
- Physical
- Reliability
- Security
- Quality
- Compliance with laws

- Safety
- Calibration
- Packaging
- Disposable
- Compatibility
- Internationalization and Globalization
- Price and Cost

For an example of a PRD see the PRD template ***PRD Example***. For software only or software-intensive devices, a separate Software Requirement Specification (SRS) may be helpful to fully specify the device's operation. The format is similar to the PRD. The spreadsheet headings are used as follows.

Requirements Column Head	Requirements Column Head
ID	Each requirement has a reference number. It can be helpful to use a letter-number combo (e.g. H=hardware). Critical Subsystems can have their own letter (e.g. D=Display)
Component(s)	Component is a high-level category of the requirements such as System, Accessory, etc which is useful if the product has multiple pieces or models
Sub component	Subcomponent is related to work-effort domain (e.g. is the requirement implemented in hardware, software, both?)
Source	Can be used to show connection to a reference document, stakeholder specification or another requirement in this list
Importance	Shall = must have; Should = desired
Requirement	Details about the implementation target for each requirement. Should be pass/fail where possible. Test against PRD
Notes/Comments/Questions	Findings or logic that might influence implementation noted by architect, concept team or engineering; How does this comment modify the requirement? Is this agreed?
Updated Comments	Results of investigation into comment

Verifiable

The PRD and system requirements should be tested to show the product was designed correctly. It is done by testing every requirement in the lab. This is why specifying requirements should be done carefully. If you cannot test a requirement, you cannot verify its implementation is correct. If you have too many or conflicting requirements, the verification test will be hard to do. It's also important that the requirements accurately convey to the development team what is needed.

Best Practices for Developing and Writing Requirements

- All requirements should be testable and can fail when tested in a predictable way to prove implementation is correct.

- Make sure each requirement is complete. A requirement should reference other requirements if there are dependencies.

- Avoid duplicate requirements

- Avoid contradictory requirements

- It is preferred to write the requirement statement in positive terms. It is easier to prove a system can do something or has a characteristic than to prove it can't or doesn't.

- Requirements should be quantifiable and repeatable. Try to avoid qualitative requirements that add subjective decision making during implementation and verification.

Summary

The PRD serves as a contract between the Marketing and Engineering groups to ensure the company is creating and delivering the right product to their customers. Ensuring that all the requirements are identified can take time to analyze and develop; however, this effort is well spent providing clear design specifications to the engineers on what to develop.

About Voler System

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