

The Product Quality Assurance Plan

The Product Quality Assurance Plan consists of key test methods that guide the team in determining whether a product is meeting customer expectations.

As a new product development project progresses through its commercialization phases, the Product Quality Assurance Plan becomes more detailed. Laboratory or pilot scale data is eventually replaced by full scale production. Product specifications are determined by setting targets for each test method.

By Scale Up, the team will have optimized the raw materials and the manufacturing process to achieve manufacturing capability of each of the key test methods.

The Product Quality Assurance Plan grows into the Data Package that is handed off to manufacturing. This Data Package forms the basis of Product Process Understanding (PPU) and is a key document for the new product.

The goal of all this activity is to be able to manufacture the product *right the first time*.

The Product Quality Assurance Plan is ideally reviewed prior to each gate by a multifunctional team consisting of Quality, Lab, and Manufacturing. 3M Divisions may refer to this review in different ways, including a Design Review, completion of the Design Qualification Matrix (DQM), or Technical Quality Manufacturing Review (TQMR). The result of the review forms the action plan for the next phase.

The Product Quality Assurance Plan may be stored in PLM and can be linked to the GROW project.

Using the Product Quality Assurance Plan, the role of the Quality focus is to:

- Develop or identify robust test methods that correlate to the VOC and serve as proxies to guide product design and assess manufacturability
- Develop product specifications to define critical performance characteristics based on known variability
- Use statistics and experimental design to identify trends, control limits and product specifications
- Confirm manufacturing capability of a product or a design space
- Determine final quality plan for in-process, outgoing quality (OQC) and finished product specifications
- Work with plants to ensure translation of the quality plan and data package
- Ensure continuing Customer Quality focus throughout product Launch

The new product design also includes raw material and supplier management. The Product Quality Assurance Plan is used to confirm raw material specifications and to identify key suppliers for supply chain management.

The team also works with sourcing to determine risk and the need for second sources. Review of raw materials and any outsourced vendors is also coordinated with the Product Safety Liaison who advises on regulatory issues (TSCA, etc.).