

The Quality Mindset

What is Quality's role in commercialization?

Quality amplifies the voice of the customer (VOC) by providing a process and tools to develop a robust, manufacturable product design.

Quality assists the team in translating the VOC into Critical to Quality elements (CTQs) that can be measured by test methods. These test methods serve to guide the commercialization team to develop a Quality Plan that defines key product performance needs and leads the team to use statistics to measure manufacturing capability and optimize the product and process design. Quality also assists the team by providing critical oversight of the raw material plan and managing suppliers, as needed.

Finally, Quality also serves a voice for the unarticulated needs of a market. For example, products that are intended for electronics, semiconductor, automotive or aerospace markets have additional requirements. These additional requirements will be included in the commercialization process to ensure that the product meets all expectations and ensures the success of our customer.

What happens when we lose our Quality focus in commercialization?

The new product may not achieve its full sales potential. We may lose spec ins to our competition. Customers may file complaints, or the product may be subject to a recall. The new product may also burden our plants with low yields and high manufacturing costs.

The Quality mindset

Quality is team sport. The Quality process and tools are shared between Quality, Marketing/Business, Lab, and Manufacturing team members, who all work together to develop a robust product and ensure successful commercialization.

Quality focuses on the Customer.

- **Quality amplifies the VOC** by accurately translating the VOC into the quality plan and the product design
- **Quality sees end-to-end (E2E)** by anticipating problems throughout the product life cycle. A quality mindset works to minimize the likelihood of problems **before** they happen, rather than simply reacting to problems **after** they arise
- **Quality is a competitive advantage** when we ensure that our customers' needs are met through robust products and continued customer focus after the product launch

Systemic Process Approach

Quality brings an engineering toolkit that helps the commercialization team translate the VOC into a robust and manufacturable product. From Build Business Case phase to post-Launch, Quality provides a systematic process approach to ensure product standards are met, and the customer voice is always heard.

Quality is engaged primarily in the 3M | Grow deliverables for the Product and Process Design in each phase of commercialization. The following are among the questions that the Quality focus is involved in answering.

Build Business Case Phase:

- Has the VOC been translated accurately into Critical to Quality elements and key test methods?
- What are the failure modes of the design?
- Are there product safety risks from certain failure modes?
- Is the raw material design robust?
- Can the prototype be made on a lab or pilot scale and meet the intended technical test requirements?
- What is the variability in the data?
- Can the prototype be made several times and is the data reproducible?
- Is the product design feasible?

Development Phase:

- Which test methods will be used in product development only (“Design Level tests”), in-process during manufacturing (IP), outgoing quality control (OQC) or finished product specifications (e.g., on the Certificate of Analysis, COA)?
- Are the test methods reproducible and accurate (Measurement Systems Analysis, MSA)?
- What are the product specifications?
- Can we verify that we meet the product specifications?
- What is the variability among the lots run to date? Can we estimate a CpK or PpK?
- Is the raw material design robust (second sources, business continuity, approved suppliers, etc.)?
- Has the product been validated with customer testing?

Scale Up Phase

- Do multiple runs on the manufacturing line demonstrate process capability (CpK or PpK) for each critical test method (IP, OQC, COA)?
- Are the process risks known (e.g., pFMEA) and are those risks addressed in a control plan?
- Are all test methods verified (MSAs complete)?

- Has the product been validated by testing at the customer(s)?
- Are the product specifications finalized?
- Have all additional quality requirements been met to address industry standards or regulations market (e.g., SPC, APQP, PPAP, CpK > 1.33, IATF-16949 or AS9100 certifications, etc.)?