

Process Qualification (Product Qualification)

Definition:

Process Qualification (sometimes called “Product Qualification”) is a system used to evaluate the adequacy of the product design and to determine if the product design can be manufactured at the projected cost and quality. Then the next step is to determine the degree that the manufacturing process degrades the intrinsic performance level of the design when it is in mass production. Reference – IBM Technical Report TR02.901- released in September 1981, authored by H. James Harrington.

The system qualifies the product and the process that produces the product at three different levels of the product cycle – in development, before design release and at the hard-tooled production level.

Benefits

- The development production process is defined and the product key parameters are documented.
- The reliability of the development product parameters are measured.
- The measurement accuracy of the development equipment is evaluated.
- The product that is used to define the production process is documented, controlled and evaluated.
- The process that produces the model products that are used to make the decision to sell the product is controlled and documented.
- The design manufacturability potential is accessed before the engineering documents are released and the product is announced for sale.
- The degree that the manufacturing process is capable of meeting a Cpk of 1.4 is defined.
- Each step in the potential manufacturing process is certified before the product goes into production that is shipped to a customer.

- The product is tested in customer-simulated environments prior to going into production and when the hard-tooling production line is up and running.

Qualification System

The process/product qualification is made up of three major phases. (See Figure 1.)

- Phase I. Development-level qualification
- Phase II. Pre-design release level qualification
- Phase III. Manufacturing hard-tooled level qualification

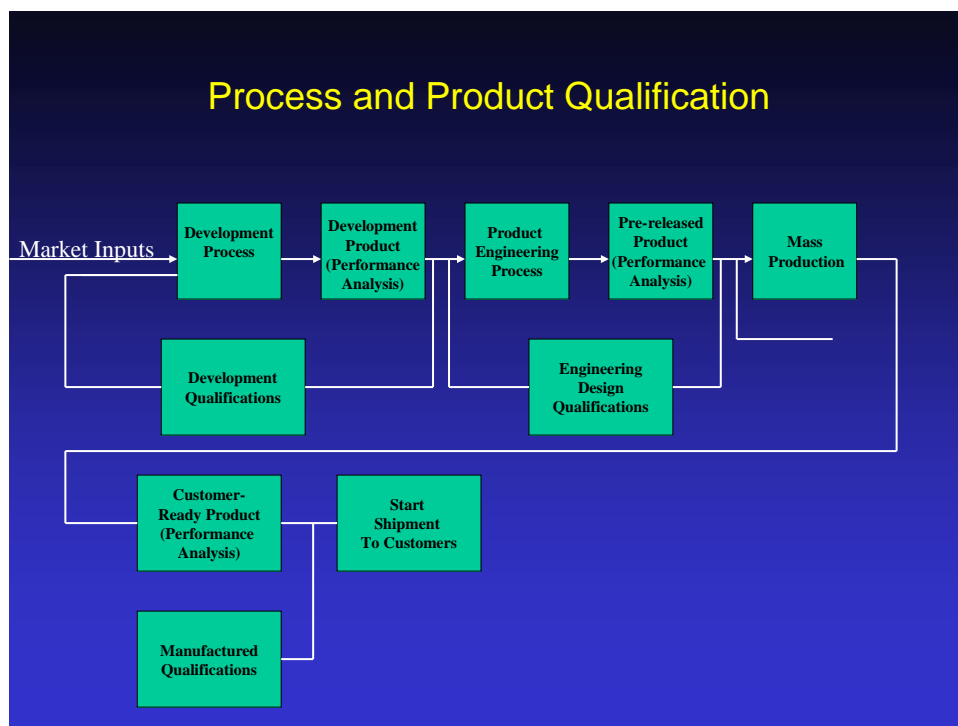


Figure 1. Process and Product Qualification

At each of the three phases each step in the process that creates the output is certified and the output is evaluated to measure its performance compared to the way it would be used in the customer environment plus the output (product) is subjected to a set of stress tests to provide added confidence in the product.

Development product and process

The development lab process that produces the concept models that are used to make the decision whether to go into mass production or not are usually poorly controlled and documented. The need to have a controlled documented-development process is important but the way it is managed can not impact the creativity of the development personnel. To do this, the development team is made up of development engineers, manufacturing engineers, test engineers, quality engineers and manufacturing technicians. This joint team works together to produce a working model that can be evaluated for its marketing potential. The mock up model that the development process produces is key to defining sale-ability of the product and defining the performance specification. This product is usually produced by highly trained and skilled laboratory technicians using equipment that isn't practical to reproduce in the manufacturing environment. The qualifications of this level enable the process that produces the development mock up model to be documented and the equipment that produced it to be evaluated for its accuracy. It also enables an evaluation to be made of the potential of meeting the proposed specification in a production environment. It also provides a means whereby the product that is subjected to the off-line testing activities can be duplicated and reproduced. Failure to meet the Phase I qualification requirement will result in the product not being approved to move into the next phase of the product cycle.

Product Engineering Design Phase

The next certification level is at the Product Design Release Level where formal design is available and ready for release. At this point pre-production models are prepared based upon the proposed engineering pre-released documentation and documented model build operation. At this level the process that produces the product is documented and each step in the model build process is evaluated to determine the accuracy of the equipment, the activities that are involved in producing the product and the results of each inspection activity. The output from the certified process will be subjected to customer simulated environmental and life tests. This evaluation is used to certify each of the steps in the engineering production process. This includes an evaluation of the purchased parts and

materials. Often the suppliers used by the engineering departments are not the same ones that will be used when the product goes into mass production as purchase price is much less important when you are building 10-20 versus 100,000 units.

When the Product Engineering model product and processes that produce the product are qualified, the design will be released to manufacturing. The product now has developed to the point that the organization can start talking about delivering it with external customers.

Final qualification of customer-ready product and processes

Once the manufacturing processes are installed with proper procedures, approved suppliers and hard tooling, each step in the manufacturing process is certified to determine if it will meet a C_{pk} of 1.4. To accomplish this, each step is operated by a number of different people and the equipment is torn down and reset up a number of different times so that the variation between operators and set-ups can be adequately evaluated so that a projected C_{pk} can be defined. Those operations where a C_{pk} of 1.4 cannot be obtained will have inspection control put in place until a C_{pk} of 1.4 can be established. The products that come off the qualified process will then be subjected to customer simulation and stress testing prior to first customer ship. Failure to meet the Phase III qualification requirements will keep products from shipping to external customers.