Stop Inspecting for Quality. Build In Quality from Day One.

Testing and inspection are an expensive way to manufacture and deliver quality products and services. Building quality into your products starts during the design phase by setting the right specifications and the careful evaluation of potential suppliers.

The quality of a product or service is established during design. It is then achieved through the proper control of the manufacturing process or service delivery.

An effective quality management system follows several critical steps:

1. Determining the processes and responsibilities necessary to attain the quality objectives
2. Establishing methods to measure the effectiveness and efficiency of each process
3. Determining means of preventing non conformities and eliminating their causes

During the design phase the quality management team sets the quality objectives and specifies the operational processes and related resources to fulfill those objectives. This begins with clearly stating the specifications with which a product, process, service or other activity must conform. These can include process or test specifications, or relate to the product itself, including product characteristics, performance levels, and engineering drawings.

During planning, supplier control determines what will be acquired and what the products or service must provide. Supplier evaluation should start once the technical requirements are stable and include the review of current suppliers' historical performance. A risk profile can help identify the inherent safety and business risks, and how to mitigate those risks.

The technical, quality and business specifications include:

Technical Requirements	Quality Requirements	Business Requirements
• Links to the design control process • Critical to quality (CTQ) specifications • Essential outputs • Technical risk analysis performance by a cross-functional team • Actions needed to mitigate high risk areas	• Quality assurance procedures, standards and other requirements necessary to ensure that the product or service is adequate for its intended use • The processes that require validation including product assessment and rework approach • The change notification process when the supplier should provide information on any changes to the qualified process	• Non-disclosure / confidentiality • Price • Performance • Business continuity /disaster recovery • Logistics

Identification of Risks and Controls

As part of the planning activities, design teams should identify risks associated with the products or services to

be obtained. Due consideration should be given whether the part is custom built or off-the-shelf, as well as the manufacturing complexity. If the part is critical, one needs to determine if a failure mode and effects analysis (FMEA) was conducted and review the risk priority number (RPN) and mitigation plans.

The experience level of the supplier should be considered as well, especially if this is their first attempt at making the specific part or type of part.

Business risks for potential suppliers include:

- Financial viability of the supplier
- Continuity of supply
- Liability
- Amount of work awarded to supplier in relation to the supplier's overall capacity
- Capital investment
- Single source suppliers
- Company legal status

The identified risks – including any regulatory requirements -- should be evaluated to determine the type and extent of controls needed. These controls should be defined and documented and include any quality requirements. Manufacturers often evaluate first-tier suppliers but do not give enough consideration to second- and third-tier suppliers.

Potential controls include:

- Supplier audits
- Testing and verification
- Certificate of analysis
- What to measure and how
- Measurement system analysis
- Environmental compatibility
- Reliability
- Process capability and Capacity
- Process validation
- Response times
- Statistical process control
- Rework
- Inventory control – First in, first out; time limits

- Batch sizes
- Traceability – process, product, equipment, operators
- Change Control – changes to process, parts, procedures
- Protection of intellectual property
- Document retention periods
- Quality system records

Receiving and Acceptance

Finally, quality engineering must establish and maintain procedures for receiving and acceptance of incoming product. These procedures include inspection, testing and verification of conformance to specified requirements. Acceptance or rejection should be documented.

Incoming acceptance activities include the following:

- Observation of production at source
- Inspection at source
- Certificate review: conformance or analysis
- Independent confirmation of certificate data
- Review of process monitoring data

Quality management oversees all activities that must be accomplished throughout the life cycle of a product. This includes the creation and implementation of quality planning and assurance, as well as quality control, while dealing with any gaps through quality improvement. When a product or service exceeds customers' needs and desires – of which quality is a key factor – it can create customer delight contributing to customer loyalty and long-term success.

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Nero Haralalka has extensive experience in lean manufacturing and back office process improvement. He is one of our leading subject matter experts in statistical problem solving.