



Quality System & Process Control Examples

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Quality Information Types

- ❑ **Quality System** - Quality System Documentation in support of ISO certification, Good Manufacturing Practices (GMP) Audits
- ❑ **Corrective Action** - Feedback & follow-up on process or product problems identified throughout the business: supplier, mfg., assembly, service, customer...
- ❑ **Process/Product Control** – Material and manufacturing measurement, process parameter control & product control vs. spec.
- ❑ **DPU - 4-Up Chart** - Summary of Product Flow DPU and Defect Trends
- ❑ **Cost of Quality** - Costs of Internal & External Failure, Appraisal & Prevention - prioritize / cash improvement
- ❑ **Process Capability** - Summary process data used by design teams to evaluate product supplier / mfg. capability

Vision for Quality Information Tracking

- ❑ Data is entered into a system only once
- ❑ Seamless & Direct Quality Information Flow
- ❑ Real-Time Data supports Continuous Improvement
- ❑ Product and Process information and reports are readily available and automatically generated
- ❑ Report users pull required data from data sources rather than requiring customized reports from suppliers
- ❑ Common processes in use - facilitate program start-up
- ❑ System and platform varieties are minimal
- ❑ More is time spent on improvement than on reporting
- ❑ Systems are linked: Quality, ERP, Financial, Execution...

Typical Problems

- ❑ Many processes don't have SPC or even SQC on product characteristics
- ❑ Don't do enough process variable control to be a Six Sigma organization
- ❑ Lack central real-time process control visibility in many areas
- ❑ Data is not stored in a meaningful way - have to do special study
- ❑ We don't do a good job converting tons of data into information
- ❑ Measuring device capability to download measurement capability / data is not used (Test Capability index - TCI, gage R&R)
- ❑ SPC & shop floor control processes aren't integrated. Need to integrate process control system into QMES
- ❑ Lack full understanding of QMES and links between shop floor control and quality / SPC
- ❑ Product genealogy tracking isn't robust or is absent in current systems

Example Process

Today's Process Control, Process Capability



- Collect Process Data on the production floor using manual tracking forms or local system
- Prepare Statistical Analysis: SAS, Minitab, etc.
- Meet with Design Team - share reports
- Use data to determine manufacturability - Design Team

*Consensus that this is a Critical Need to support
Six Sigma Design for Manufacturability*

Future - Best Practice Process Control, Process Capability



- Use Quality Management Execution System (QMES) and Statistical Process Control (SPC) Systems to gather data at the process and maintain process control
- Summarize Data in a Shared Process Database
- Incorporate Data into process models
- Use process models to evaluate and improve design specifications to match process capability - Design Team