Proactive Quality Management Requires Integrated Execution

Over the years, quality control has evolved from practices focused on final product inspection by a quality inspector to practices that rely more on in-process self-inspection by the production technician and a much smaller auditing role for the inspector. Most quality professionals agree that it is much less expensive and more effective to design quality into the process rather than test and fix products at the end of the process.

Inspection of the product after it is made results in costly rework, scrap and delays. Quality professionals must consider how to best control potentially problematic processes during manufacturing to ensure acceptable quality at the end.

Today’s manufacturing technicians manage their own quality as part of their work processes; inspection requirements are built right into the manufacturing work instructions; and verification mechanisms are built into tooling fixtures and work procedures. These additional inspection requirements for the technician can be simplified and automated by a Manufacturing Execution System (MES). For example, an MES can reduce the need for 100 percent verification on some processes, and instead enforce skipping or sampling rules that will automatically prompt the technician as needed. An MES can also keep track of when auditing is required by an inspector. These rules could even vary according to each technician’s experience level on different types of jobs. This level of efficiency in dispatching verifications cannot be achieved with confidence using manual methods; it requires an MES to track and enforce the rules automatically.

Reactive Quality Management

Trying to manage quality practices using a separate Quality Assurance (QA) application rather than an MES that is used by the shop floor technician is as inefficient as managing quality through final product inspection instead of using in-process techniques.

Silo QA applications, like FRACAS (Failure Reporting, Analysis and Corrective Action System), are focused on reactive practices including:

- Final Product Inspection Plans
- Documenting Problems and Failures
- Corrective Actions
- Failure and Correction Metrics

These traditional stand-alone quality applications are reacting to errors and managing the results of poor quality. Newer MES systems need to integrate quality control throughout the manufacturing process and focus on preventive practices.
Proactive Quality Management

Although it is important to track defects, find the root cause and follow up on corrective actions, it is also important to manage quality proactively to reduce the opportunity for issues in the first place. If your organization does not include an MES in the evaluation of a quality management solution, you can be missing out on the following proactive quality management functions, which should be provided by an MES:

- Process Standardization and Visual Aids
- Process Enforcement
- Configuration Verification
- In-Process Inspection
- Statistical Process Control (SPC)
- Production Process Verification
- Personnel Qualification
- Tool Control
- Device History Records

Process Standardization and Visual Aids

Standard procedures should be documented for commonly used manufacturing processes, and personnel should be trained on these procedures. Clear work instructions should be provided for each manufacturing step to further ensure process repeatability.

Pictures, 2D and 3D illustrations in work instructions are very useful to clarify tricky work sequences and prevent incorrect operation. The integration of CAD/PLM systems can be critical in some industries to ensure that 2D and 3D visualizations of the product and process reflect the correct engineering revision level and configuration.

Process Enforcement

An MES can enforce many aspects of the manufacturing process to help ensure repeatability and consistency. An MES can enforce a prescribed sequence for operations and make sure that operations cannot be signed as complete until certain data is collected. Along with enforced controls comes the need to handle exceptions, therefore, an MES must also provide easy methods for handling deviations that have been approved for specific units or lots by the appropriate personnel.

Configuration Verification

Organizations that assemble products with complex configurations and variations need to ensure that all component parts are coming from the correct bill of material (BOM) at the correct engineering revision level. An MES integrated with an Engineering system can ensure that the list of parts reflects the proper component parts and cross references to any incorporated Engineering Change Notices (ECNs), approved deviations and part alternates.

In-Process Inspection

In-process inspection verifies critical product attributes and characteristics during the manufacturing process, and are usually performed by the technician instead of the inspector. These measures can relate directly to the product specifications or to intermediary dimensions specific to a production process, tooling fixture or machine setup.

In-process inspection points should be inserted prudently as early in the process as it is reasonable. Decisions for inspection points and frequency are based on historical data collected by an MES and should be adjusted over time to address any problem areas.

Some MES systems allow specification of random over inspection and audit rules to dispatch a quality inspector to verify that the technician is performing good measurements.
Statistical Process Control

Statistical Process Control (SPC) is a technique that utilizes statistical methods and control charts on collected data to detect and control variation, change, inefficiencies and deficiencies.

SPC serves to:
- Produce early warnings on out-of-control processes before out-of-spec products are produced
- Detect out-of-spec products immediately at the data collection point
- Detect process inefficiencies that are otherwise hard to find with manual systems

Control charts are used to detect unexpected variations in processes. When a process shows variation with an unexpected, non-random pattern, such as a shift, trend or cycle, the process is unstable, unpredictable and “out of control”.

Specification limits (spec limits) define the range of deviations that is considered by the design engineer (or the customer) as acceptable. In contrast, control limits used in SPC are calculated based on the actual measurements taken at the process or machine. Control limits are adjusted by the system automatically based on the trend of actual measurements to (1) determine the real capability of the process compared to the expected capability and (2) to predict out-of-control trends before they lead to out-of-spec conditions.

Locations of the observations relative to a control chart’s control limits (typically at ±3 standard deviations) and centerline indicate whether the process in question should be investigated for assignable causes. These Western Electric rules are examples of how control limits are used to trigger proactive “out-of-control” alerts:
- Any single data point falls outside the 3σ limit from the centerline
- Two out of three consecutive points fall beyond the 2σ limit on the same side of the centerline
- Four out of five consecutive points fall beyond the 1σ limit on the same side of the centerline
- Eight consecutive points fall on the same side of the centerline

Production Process Verification

Production Process Verification (a.k.a. first article inspection) is the inspection of key and critical attributes and characteristics on the first item(s) produced from a new product design or a significant process change, in order to verify the capability of the process to produce the desired results.

These process verification requirements are usually not implemented as in-process inspections; they are usually performed on the completed product unit. However, there are advantages to triggering these additional inspection requirements directly from an MES system since it can ensure that every significant change to a process plan or work instructions will trigger the respective additional inspection requirements.

Personnel Qualification

In addition to enforcing process sequence and data collection, an MES can also enforce that personnel is qualified to perform a job. These verification requirements are considered part of quality management system requirements in industry standards, including ISO9001, AS9100 and ISO13485.

An MES can verify that personnel skill certifications are up to date before performing any work to ensure that employees are qualified to run specific manufacturing equipment or handle certain materials or resources.

Tool Control

An MES with integrated tool calibration management can automatically verify that a tool or gauge used is still under calibration and is appropriate for the tolerance required. An advantage provided by an MES is that recalibration can be triggered based on tool usage and not strictly on dates.
Device History Records

A side effect of enforcing the product configuration and collecting all the manufacturing data during the work process is the automatic creation of the device history record or as-built documentation for each product unit. Some QA organizations have people dedicated to collecting log books from the shop floor and manually verifying that all the appropriate forms have been filled out. This function can be fully automated with an MES system for organizations that have to assemble this type of paperwork as part of the documentation package that is delivered with the product to the customer.

Summary

Organizations evaluating QA and MES applications as separate applications for separate department silos are likely to miss out on a great opportunity to elevate quality management to a proactive function. QA applications evaluated separately tend to focus on reactive practices like FRACAS. MES evaluations performed without considering the needs of quality management are usually focused on visibility of schedules, statuses and performance metrics. So it is easy to miss out on the proactive quality management functions listed above.

In today’s fast pace manufacturing world, we cannot try to inspect quality from the side lines. We must manage quality from the inside and throughout the entire manufacturing process with an MES that integrates inspection practices and verifies the certifications of personnel, tools and machines. It is not enough to simply track defects, failures and corrections; we must integrate quality management practices that prevent errors and catch them as early as possible. Technicians must be responsible for their own quality and an MES can help them do it.

Author

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