

How to Achieve Significant ROI Through Advanced Quality Management Practices

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ABSTRACT

This session is an overview of best practices in Mission Assurance & Risk Mitigation to meet the challenges of today's space leaders. Gain an understanding of how to meet stringent compliance and launch requirements within the space industry and deliver higher quality products using a fully integrated quality management system. Steps to ensure project success and rapid return on investment will also be discussed.

THE NEED FOR ADVANCED QUALITY MANAGEMENT

Companies need to practice advanced techniques in order deliver higher quality goods, as well as adhere to industry compliance standards and regulations. Implementing best practices in quality allows for an examination of costs associated with poor quality such as scrap, rework, and warranty/recalls.

Audit Readiness

The issue of electronic-based QMS is getting more and more attention from the US Congress. It has received little attention but buried in the recent Defense bill signed into law contains a provision that states:

Defense Authorization language. Sect 820:

"The conferees also encourage the Director, Defense Contract Audit Agency (DCAA) to examine the potential for electronic quality management systems to improve the ability of DCAA to conduct thorough and timely audits."

With the ability to set up supplier-specific or regulation-specific pre-audits, audit readiness is guaranteed.

THE BENEFITS OF AN ELECTRONIC QUALITY MANAGEMENT SYSTEM

A modern electronic quality management system (QMS) can tackle problems within your supply chain and streamline processes to improve overall product quality. An effective quality management software solution is the key to dramatically improve the entire quality process from source inspection through final device approval and product shipment.

A Best-in-Class QMS Delivers the Following:

- Real-time Access to Quality & Manufacturing Data
- Control Over User Access
- Automation of Critical Quality Processes
- Visibility into Costs
- Effective Collaboration with Suppliers
- Ensures Operational Excellence throughout the Product Lifecycle

MANAGE RISK THROUGH VISIBILITY AND COMPLETE TRACEABILITY AT EVERY STAGE OF THE MANUFACTURING PROCESS

Complex manufacturers require accurate reporting to avoid expensive rework and reduce the time and expense of product recalls. With an effective quality management software solution, manufacturers can ensure quality compliance and complete traceability throughout the product lifecycle. Genealogy for all material, parts and finished products can be documented as part of the audit trail. Quality records can include associated as-built/as-maintained configuration records, nonconformance dispositioning, approvals and comprehensive quality data history.

Genealogy/Configuration Management

- Enforcement of Requirements (*Serial Number, Lot Code, UID, etc.*)
- Ensure all issues are resolved before product release
 - All inspections completed
 - All Nonconformances resolved
 - All deviations approved
- Ability to rapidly identify suspect material for recalls

MEET STRINGENT COMPLIANCE REQUIREMENTS WITHIN THE COMMERCIAL SPACE INDUSTRY

In an industry such as Aviation, Space and Defense it can be difficult to keep pace with evolving standards. Regulatory standards such as ISO9000 / AS9100 / QS / IPC Standards / Mil Spec Requirements change on a regular basis. Using advanced quality management techniques, a company can employ processes to ensure compliance throughout the product lifecycle. An industry-leading solution can address ITAR requirements, Federal Acquisition Regulations on counterfeit parts, ISO Audits & Certifications, Government Audits, and Supplier Audits.

Compliance Challenges Can Be Met with Ease

- Electronic Supplier Survey and Audit Scheduling process
- Compliance Audits including Closed Loop CAPA to Track all Findings
- Ensure compliance with ISO, MIL Standards
- Certified Operator Audits
- Safety Audits and Findings

A Sampling of Standards Includes:

- ISO 9001
- AS9100, AS9102, AS5553, AS6174
- FDA 21 CFR Part 11
- DoD Flow Down

IDENTIFY SUPPLY CHAIN RISKS AND LEARN TO IMPROVE SUPPLIER PERFORMANCE

An effective quality management software solution provides a systematic view of incoming data with real-time metrics that allows managers to make informed decisions by accurately assessing risk. Managing suppliers through every tier of the supply chain is a critical step to mitigate the growing burden of risk. A QMS with supplier management functionality manages the quality lifecycle of both suppliers and sub-tier suppliers. The solution provides complete visibility into the supply chain and helps hold suppliers accountable for poor quality. Supplier approvals, certification, and performance measurements can be managed within the system. Product inconsistencies alert manufacturers to nonconforming material that must be recalled. In short, a quality management software solution allows companies to effectively manage their supply chain to drive down cost and eliminate errors.

Mitigate Risk Within the Supply Chain

- Understand the true cost of quality using key performance indicators
- Explore provider-related costs and data to hold poor performers accountable
- Ensure compliance and audit history by tracking regulatory requirements
- Proactively monitor suppliers based on performance trends
- Associate first-tier suppliers to their sub-tier suppliers for improved traceability
- Improve security with encrypted access to supplier data

Manage the Supply Chain

A standardized approach to managing supplier information allows you to map your supply chain and indicate primary and sub-tier supplier relations. Advanced quality and supplier management techniques allow for easy identification and categorization of suppliers.

For example:

- Authorized Distributor
- Franchised Distributor
- Independent Distributor
- Open Market
- OCM/OEM

CONTINUOUS IMPROVEMENT TECHNIQUES LEAD TO HIGHER QUALITY PRODUCTS

Companies practice advanced quality management to achieve continuous and measurable improvements and advance customer service, productivity and profitability. It is important for a company to build a comprehensive continuous improvement strategy. Quality management is an ongoing responsibility that extends beyond an organization's walls to both suppliers and customers. Use of an effective quality management software solution enables companies to manage the process in its entirety – with the functionality and flexibility to do it well.

Nonconformance/MRB Approval

- Split Dispositioning
- Multiple Defects per Document
- Traceability by Lot Code, Date Code, Heat Code, Serial Number
- Parent Child Relationships
- Root Cause Failure Analysis
- Task Planning

Electronic Receiving Inspection Process

- All Attribute and Variable data collection
- Inspection Instructions
- Electronic Vaulting of all Incoming Certifications and other required documentation
- First Article Requirements Notification and Electronic Vaulting of Supplier First Article Reports
- Tracking Tool and Gauges used on Specific Inspection Records
- Employee Skill Validation

Product Manufacturing Inspection, Test and Process Control

- Manufactured Product Inspection Instructions, Attribute Results and variable Data Collection
- First Pass Yield for all Critical Test Operations
- Electronic loading Variable Data Collection Attributes (Example: From DISCUS)
- Employee Skills Validation and Tracking
- Defect Collection
- Closed Loop CAPA Process for Internal Corrective Actions
- First Pass Yield Data Collection and Reporting
- Configuration Management - As-built Data Collection
- Serial Number Assignment
- Release, Vaulting and Electronic Distribution of Quality, Manufacturing and Engineering Documents Supporting Operations

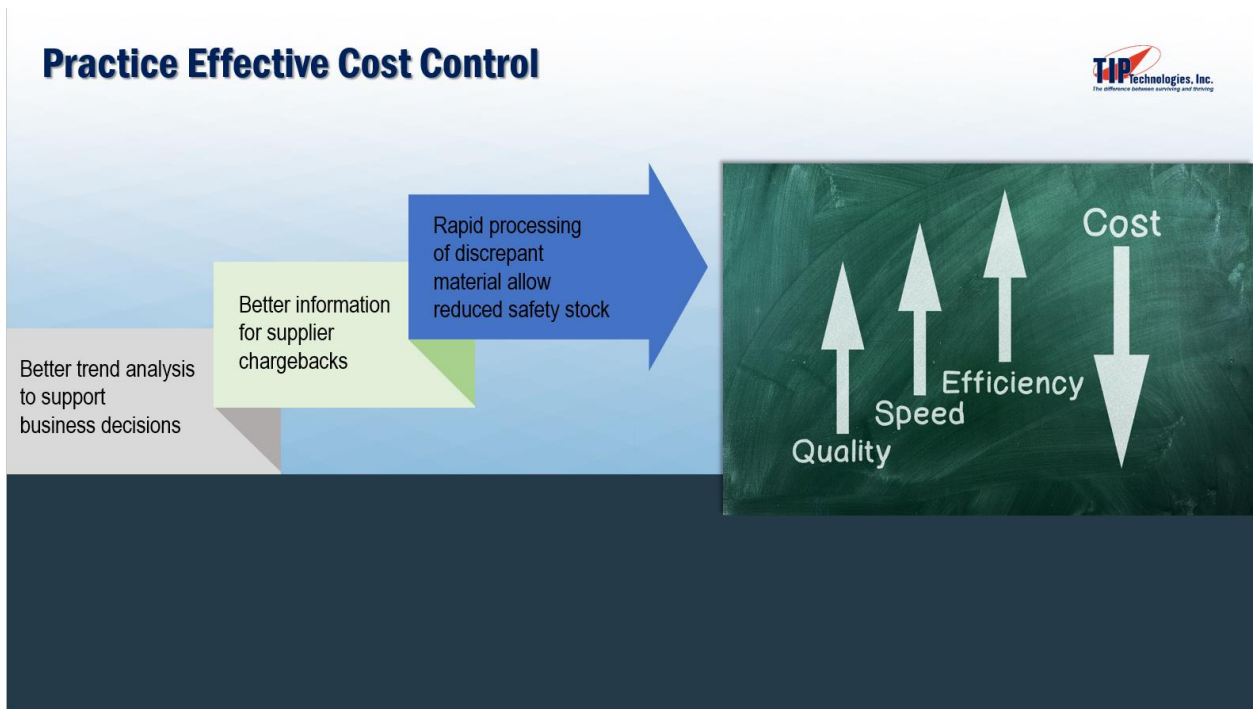


Exhibit 1: Practice Effective Cost Control

A PAPERLESS SHOP FLOOR IMPROVES EFFICIENCIES

An effective quality management software solution with shop floor execution capabilities will allow companies to efficiently manage daily production processes on the shop floor and automate quality compliance with a single solution. Complete visibility into the inspection process and inspection documentation history allows manufacturing and quality teams to work together for greater control of the manufacturing process, and

immediately identify potential for costly errors without slowing down production. Quality data can be merged with a company's ERP solution to get a true picture of what is happening within the organization.

Streamline Operations on The Shop Floor

- Seamlessly Integrate Shop Floor Data & Quality Data
- Reduce the Cost of Labor by Eliminating Redundant Processes
- Electronic Work Instruction Authoring
- Validate shop floor skills requirements such as FAA, FDA, AS9100, & EASA
- Provide a Comprehensive & Systematic Approach to drive quality throughout the organization
- Create "a single view of the truth" in regard to Quality

ADVANCED QUALITY FOR THE SPACE INDUSTRY

Quality is paramount to companies in the Aviation, Space and Defense Industry. Delivery of high quality products is vital to customer satisfaction and if quality falters there can be severe safety consequences. In addition, Aviation, Space & Defense manufacturers rely on vast supplier networks to bring their final product to market and need an effective means of communicating with their vendors. Often companies within highly regulated industries such as the newly emerging commercial space market rely on a quality management software (QMS) solution that delivers more functionality than what is available in a typical ERP solution. To support best practices in quality and compliance, these companies choose a QMS that is built to support rapid innovation and an evolving regulatory environment.

Competitive Advantage for the Space Industry

- Support Mission Assurance and Regulatory Compliance
- Minimize the Risk of Counterfeit Parts
- Modernize MRO Processes, Lower Expenditures and Compliance Risk
- Manage the Quality Lifecycle of Your Suppliers and Sub-tier Suppliers

ASSESSING RETURN ON INVESTMENT

Choosing new quality management software can be a big decision. Given a need for quality improvements, it is imperative that the solution delivers a return on investment as soon as possible. Effective quality management software can make a big difference in a company's manufacturing operations and can help create a culture of continuous improvement. The benefits quality management software presents are numerous. Some can be quantified, while some are more intangible that take place over time. However, the most important is the fact that quality management software can put manufacturers on the path to be more proactive versus reactive, resulting in improved overall quality.

To help you understand your return on investment, we have provided some indicators that you can use to track your progress.

Impact on ROI – Directly Measurable

- Reduced supplier management costs
- Increased vendor recovery success ("Game Changer" level of increase)
- Reduced defect management costs
- Reduced labor hours to maintain and improve quality operations
- Reduced IT support & costs

Impact on ROI – Soft Return

- Ensures compliance & reduced risk throughout the product life cycle
- Visibility into overall operational performance for better decision making
- Improved confidence and quality of products shipped
- Complete traceability, track-ability, and genealogy of every part, subassembly, and final assembly

WHAT TO LOOK FOR IN CHOOSING AN EFFECTIVE QUALITY MANAGEMENT SOFTWARE SOLUTION

There are many things to consider when looking for an effective quality management software solution. Functionality should not be the only driver in selecting a solution. Factors such as vendor experience, industry reputation and ERP integration should also be considered. The ability to deploy the software with the flexibility to adapt to current business processes is key.

Important Features for Companies in the Space Industry

- Choose a solution to manage CAPA, NC, RI, Audit
 - Test for and capture defects throughout entire lifecycle for each component
 - Captures all artifacts to support capture of “As Built” versus ERP standard builds
- Choose a solution to manage mission assurance
 - PRIME - Tier 1 – Tier 2 – Tier 3 and their subs
 - Contractors and subcontractors (ERP systems do not track subs)
- Choose a solution to support paperless manufacturing on shop floor
 - Paperless execution, supported by QMS to provide MES at reasonable investment
 - Seamlessly passes all data to quality solution for reporting and audit control management