A COMPREHENSIVE GUIDE TO QUALITY CONTROL FOR SMALL MANUFACTURERS

A guide for understanding which approach is best for your specific manufacturing business.

Overview

Many small and medium size manufacturers don't have in-house resources like an industrial engineer who can bring in up to date methodologies and equipment to help the facility stay ahead of its competition. With quality control measures now multiplying to cover almost every part of the manufacturing process, it is more important than ever for small manufacturers to ensure they have the means to reduce waste and improve quality.

This white paper is intended to provide an overview of the different ways manufacturers can measure quality and be a guide for understanding which approach is best for your specific manufacturing business.

Benefits of Strong Quality Control Measures

A manufacturer's biggest priority is to ensure quality standards throughout the manufacturing process. Without up-to-date quality control measures, a manufacturer's outputs can fall short of industry and customer expectations. This can have dangerous consequences – resulting in negative press, substantial financial losses, and even lawsuits.

Image Source: NY Daily News

In the well-known example of Takata airbags, defective manufacturing processes combined with flawed QC procedures and manipulated test data created a perfect manufacturing storm, resulting in a recall of more than 69 million airbags after 13 people died and more than 100 were injured. This recall came at an estimated cost of $7 billion to $24 billion for the manufacturer. Had proper procedures been followed, lost lives and injuries could have been spared, and Takata could have avoided the largest recall in automotive history.

QC measures, however, don't simply protect a manufacturer from negative consequences, they also serve as growth drivers. The benefits of strong QC processes include:

- Decreased costs due to reduced reworking and scrap production
- Reduced material sourcing risks and costs
- Improved relationships with suppliers
- Strengthened overall market position
- A formal avenue for quickly identifying, containing, and resolving manufacturing issues

Maximum benefit is achieved when using a three-pronged approach to QC:

1. Incoming Quality Control (IQC) during the first-article inspection
2. In-Process Quality Control (IPQC) when the product is 30-50% complete
3. Outgoing Quality Control (OQC) after the product is 100% complete and when it is at least 80% packaged

Before going into detail on what entails a three-pronged approach to QC, let's first look at some of the common standards and tools available to manufacturers for measuring quality and defining KPIs and benchmarks.

What Are ISO Standards?

The International Organization for Standardization (ISO) has been setting industrial and commercial standards for more than 70 years. As the world's largest developer and publisher of international standards, ISO helps businesses achieve globally accepted quality management practices. To achieve recognized ISO compliance, a manufacturer must pass an audit performed by a third party.

ISO standards ensure that final products meet the company's quality criteria as well as improving processes around:

1. Acquiring raw materials
2. Purchasing third-party components and sub-assemblies
3. Designing and using inspection procedures
4. Complying with production processes
5. Responding to defects

While there are hundreds of ISO reference codes and series, there are five that are particularly relevant to manufacturers:

ISO 9001

This family of standards specifies the requirements for quality management systems, making it the most prominent approach to manufacturing QC and some of the most recognizable standards. ISO 9001 includes 8 general principles:

1. Customer Focus
2. Leadership
3. Involvement of People
4. Process Approach
5. System Approach to Management
6. Continual Improvement
7. Factual Approach to Decision-Making
8. Mutually Beneficial Supplier Relationships

ISO 9001 certification benefits

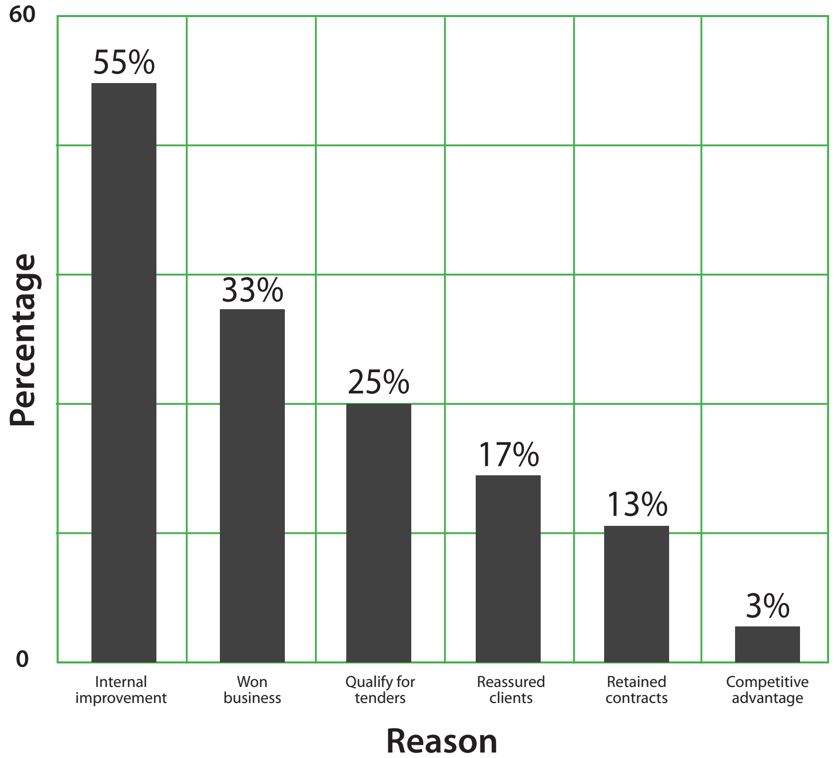


Image source: Quality Digest Magazine

AS9100

AS9100 is an individual standard is based on ISO 9001 family of standards and has additions designated for use in the aerospace industry, including risk management and configuration management.

ISO 13485

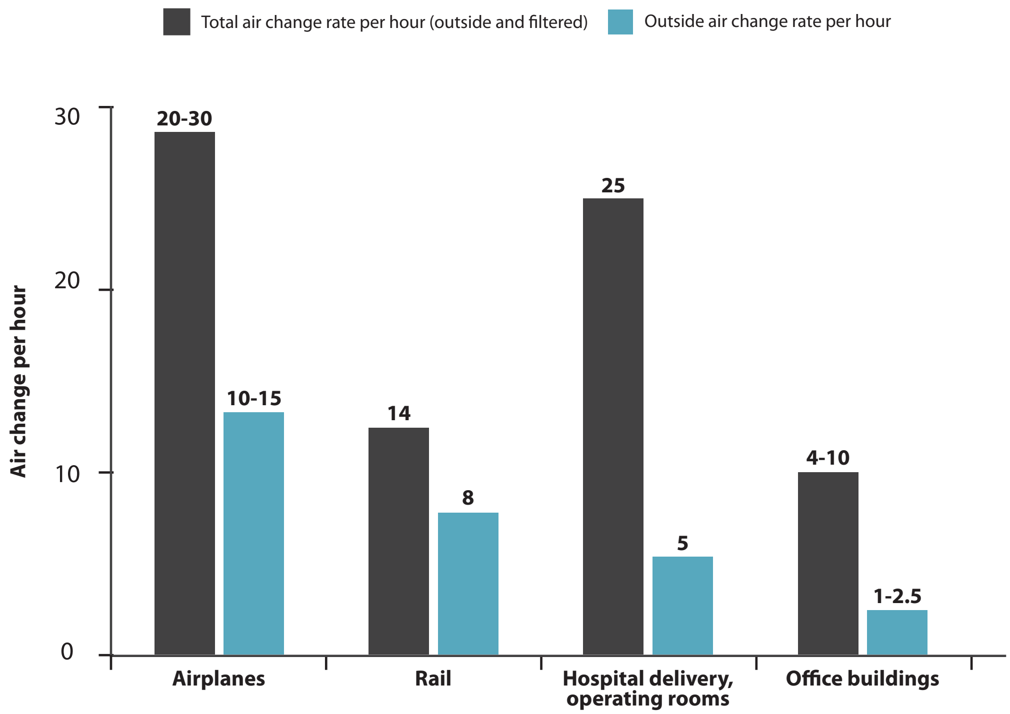
ISO 13485 is a standard for use by companies that want to design a Quality Management System (QMS) for medical devices and the regulatory requirements surrounding them.

ISO/TS 16949

ISO/TS 16949 includes requirements for the application of ISO 9001 for automotive production and service part organizations. They include all additional QMS requirements agreed upon by the main automotive manufacturers to accompany ISO 9001. Additionally, each main automotive customer that a company works with has an addendum to the TS 16949 requirements that are specific to that customer.

ISO 14644

ISO 14644 specifies the classification of air cleanliness in clean room design in terms of air-changes per hour based on air particulates. In a normal home, air-changes occur 0.5-2 times per hour, whereas clean room air-changes occur 10-600+ times per hour.



FS Cleanroom Class	ISO Equivalent Class	Air Change Rate
1	ISO 3	360-540
10	ISO 4	300-540
100	ISO 5	240-480
1,000	ISO 6	150-240
10,000	ISO 7	60-90
100,000	ISO 8	5-48

Common Tools and Processes for Quality Control

Quality assurance programs can be integrated into all aspects of manufacturing but the most common places for implementation and improvement are within statistical process control, total productive maintenance, in-coming QC, in-process QC, and outgoing QC.

1. Statistical Process Control (SPC)

Tracking production metrics provides a basis for monitoring and controlling quality throughout the manufacturing process. SPC is an organizational tool that quality managers use to identify and solve problems before products leave the facility.

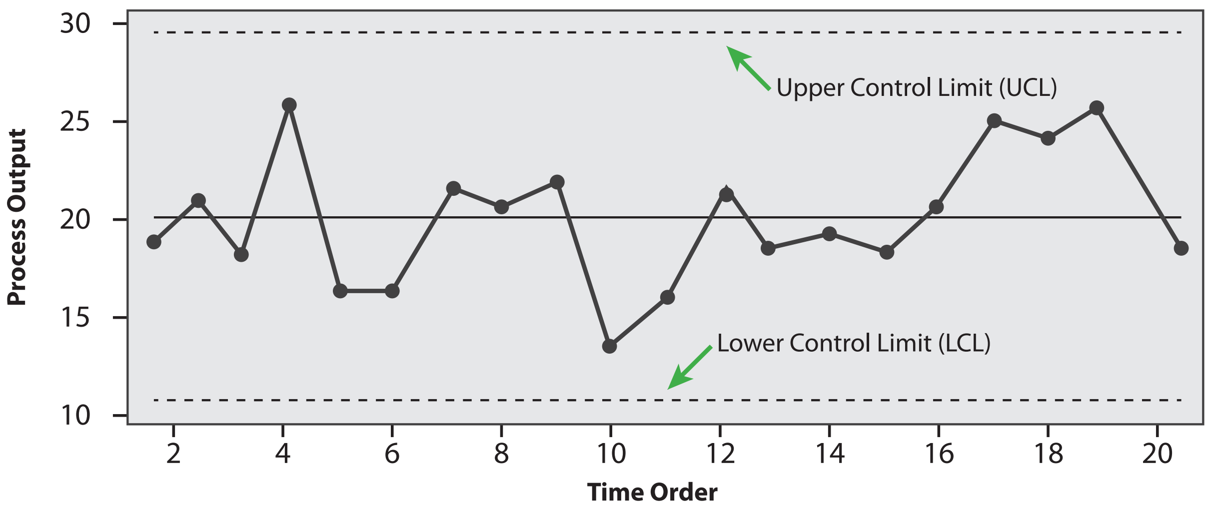


Image Source: OPEX Resources

2. Total Productive Maintenance (TPM)

TPM uses operator training and a comprehensive maintenance program to improve product quality. This approach aims to eliminate downtime, product defects, and worker accidents to lower costs and create better products.

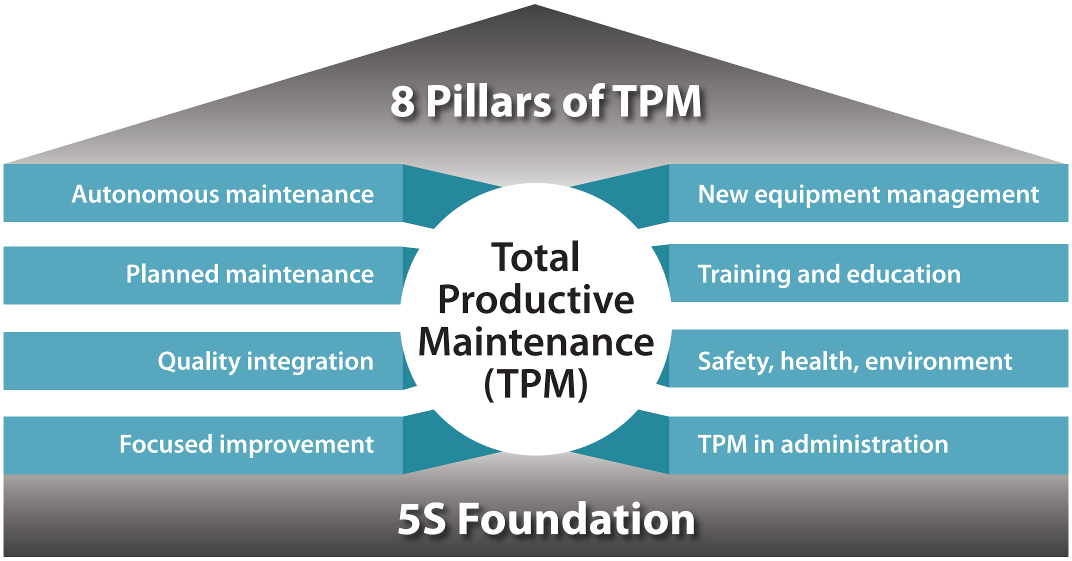


Image Source: Fiix

3. Incoming Quality Control (IQC)

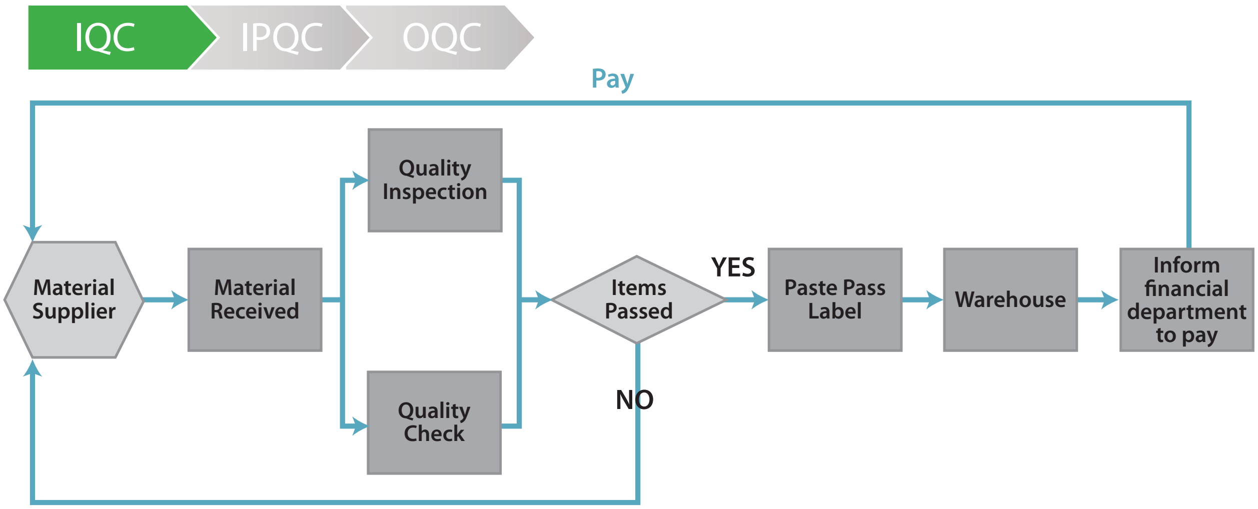
Incoming quality control is the first part of a three-step QC process, which also includes in-process quality control, and outgoing quality control.

IQC develops product criteria and specifications to include defect details so that each defect can be classified as major, minor, or critical. Once defects are gauged, inputs can then be accepted or rejected. This approach equips manufacturers to clarify acceptable quality levels and expectations for suppliers.

Raw and component materials are inspected upon arrival at the facility from the supplier and findings are then used to make business determinations. Depending on the severity and frequency of the detected defect, materials can be returned or exchanged to the supplier, as needed.

An example IQC checklist for semiconductor electronics would be:

- ✓ Evaluate supplier quality records
- ✓ Perform sampling of incoming materials based on the MIL-STD-105E standard
- ✓ Perform dimension, visual, and functional inspection of material samples
- ✓ Monitor quality control chart of inspected properties and alert engineering staff of significant deviation



4. In-Process Quality Control (IPQC)

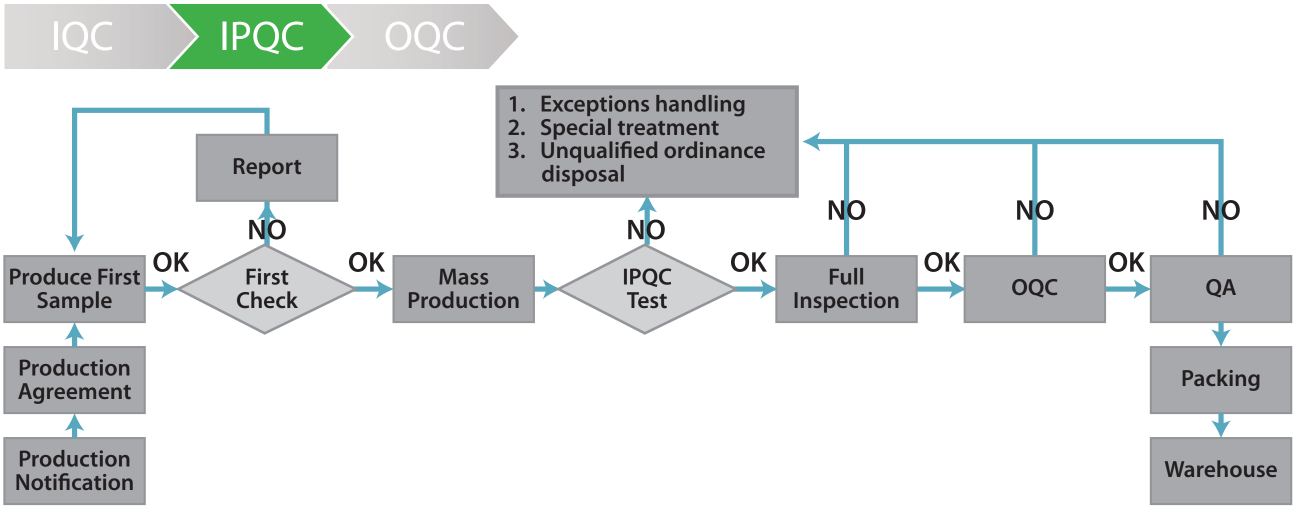
IPQC is the second part of the three-step QC process.

Sample sizes are selected for each component identified for inspection and then acceptable quality levels (AQLs) are set to regulate an accept or reject result. Inspections and product testing can help determine if specifications are being met. Where products are out of spec, troubleshooting will occur to resolve any identified issues. When used proactively, IPQC can avoid costly delays and inefficient rework down the line.

A sample case study on the production process for sheet molding compound (SMC) lightweight material illustrates the importance of IPQC. SMCs are made of glass fiber and polyester and used as a compression molding compound for larger parts where greater mechanical strength is required. With a diverse set of applications ranging from automotive and aerospace to agricultural equipment and medical devices, inline measurement systems are needed to assure high quality. If air entrapping or fiber distribution changes occur in-process, early detection is crucial to avoid a failure with the finished product.

An example IPQC checklist for semiconductor electronics would be:

- ✓ Perform inspections on assembled and in-process materials according to IPC-A-610D standards
- ✓ Conduct automated and manual in-line inspections
- ✓ Apply first-article inspection after process setup
- ✓ Utilize statistical control techniques and identify significant deviations
- ✓ Perform in-process audits to ensure processes are up to standards and identify areas that need improvement



5. Outgoing Quality Control (OQC)

As the name would imply, OQC is the final part of a three-step QC process, which includes inspection of packaging, appearance, workmanship, function, and performance.

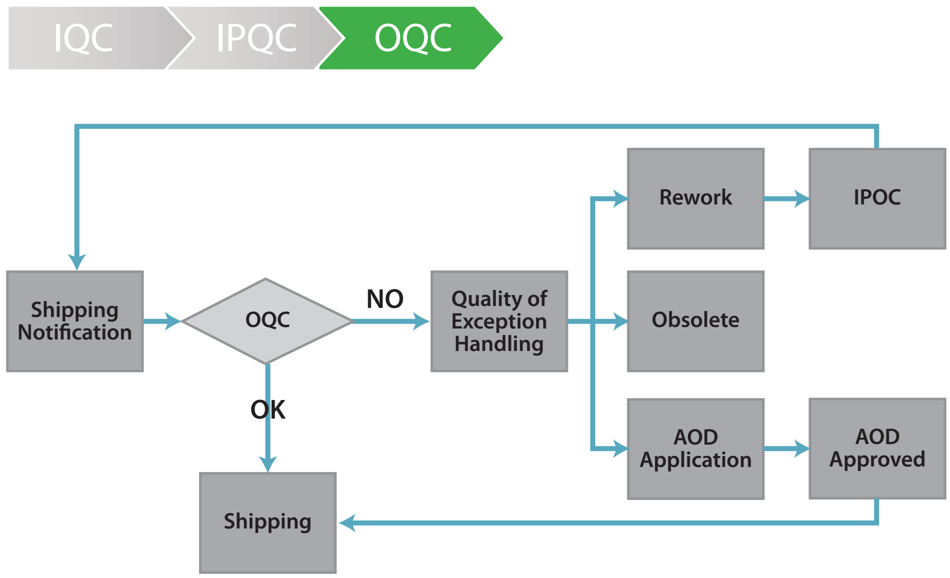
The overall condition of packaging is examined as well as accuracy of labels. This is an especially critical step for manufacturers that produce highly specialized products like medical supplies, where mislabeling could have dire consequences. Inspections may also include packaging testing, for instance drop-testing to verify durability.

Inspecting the appearance of products involves looking for cosmetic defects and missing components or accessories. For consumer goods, this is a vital step in ensuring marketability.

Function and performance testing include both the assembly itself and electrical testing as well, where applicable. These tests are meant to put the product through its paces to assess intended performance within acceptable use parameters.

An example OQC checklist for semiconductor electronics would be:

- ✓ Perform visual and functional inspections
- ✓ Verify first-article inspection
- ✓ Repeat approved vendor list check
- ✓ Apply sampling based on the MIL-STD-105E standard
- ✓ Conduct reliability testing
- ✓ Submit failure analysis reports and alert engineering staff



Results You Can Expect

Proper QC implementation can yield a bevy of results, including:

- Elimination of delays caused by changes to external processes and shop floor operations
- More accurate quality inspections
- Earlier detection of manufacturing defects and failures with faster resolution
- Flexible sampling rules and inspection plans that can be customized for the overall manufacturing process, production line, and individual product
- Automation of critical workflows and processes
- Real-time visibility and data reporting using shop floor control technology
- Faster decision-making across the enterprise
- Increased responsiveness when transferring data from shop floor to stakeholders

With 53% of manufacturers still using antiquated paper-based tracking and manual processes for QC, these benefits can be game changers. Replacing paper and spreadsheets with use-specific software allows manufacturers to be more agile and respond faster to internal issues as well as external demands.

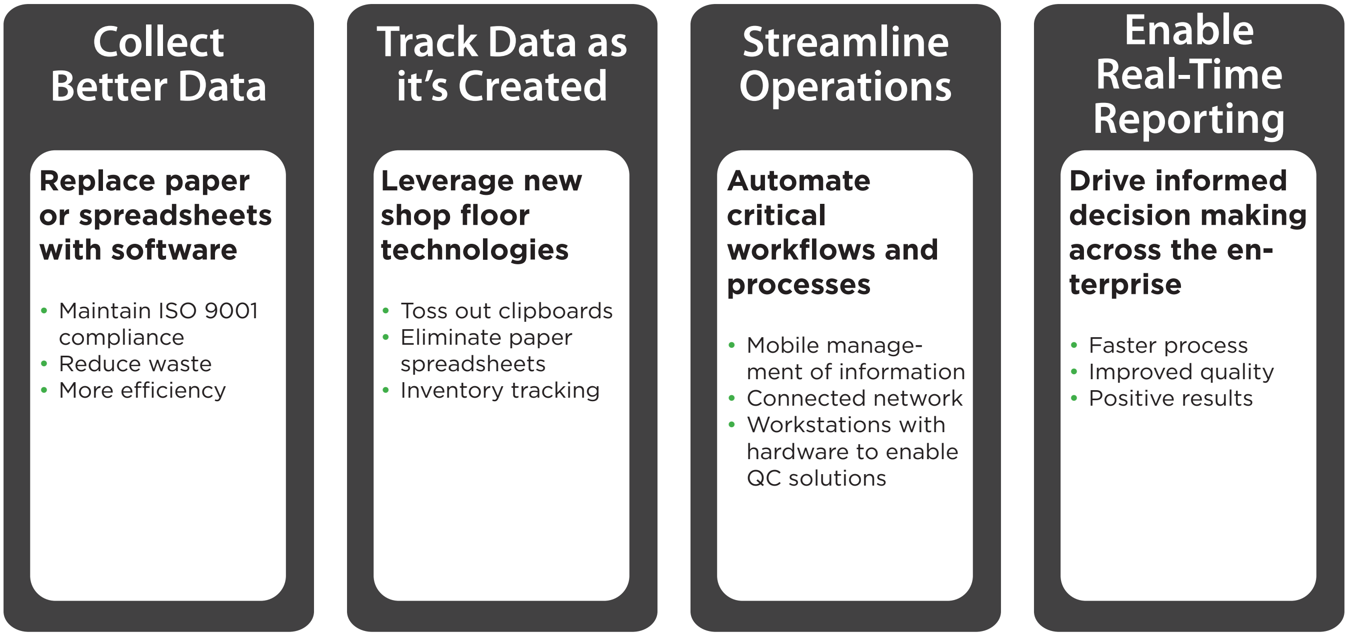


Image Source: TrackVia

An instance where mobile device usage has expanded the scope of QC processes is in the case of 5G Automatika Smart Manufacturing. As an automotive parts manufacturer, 5G Automatika sources parts from 400+ suppliers, which was resulting in a high degree of variability as well as errors and omissions in data. Their challenge was to standardize QC processes across all suppliers using data-driven methodology. Providing quality inspectors with wearable technology allowed them to gather data from gauges using mobile apps on tablets via Bluetooth technology and generate real-time reports. The result was that suppliers were able to access IPQC inspection data during every stage of production to determine which parts needed to be delivered. This reduced risk as well as the cost upon delivery, which increased both supplier satisfaction and margins. Furthermore, 5G Automatika's overall equipment effectiveness (OEE) and audit timeliness increased, increasing their profit margins as well. 5G Automatika recognized greater profits while also decreasing unscheduled downtime, maintenance costs, and worker injury rates. This solution proved highly beneficial for both 5G Automatika and its suppliers.

THE BENEFITS TO THE BUSINESS

The process improvements that result from mobile usage are directly reflected in metric performance, when compared to non-users.

	OVERALL EQUIPMENT EFFECTIVENESS (OEE)	INJURY FREQUENCY RATE (PER 100 EMPLOYEES)
Mobility	87%	1.12
No Mobility	80%	1.27

	AUDIT ACTION ITEMS COMPLETED ON TIME	UNSCHEDULED ASSET DOWNTIME
Mobility	89%	5.1%
No Mobility	83%	9.1%

	MAINTENANCE COSTS (YEAR OVER YEAR CHANGE)	OPERATING MARGIN VS CORPORATE PLAN
Mobility	8%↓	8%
No Mobility	4%↑	4%

Image Source: Aberdeen

As the data above illustrates, simply making a commitment to driving a more flexible and "mobile" workplace leads to better quality. As one of our customers recently shared in our annual feedback interview, putting the inspection devices on a powered cart eliminated the need to move product to a testing area, reducing footsteps and improving accuracy by conducting testing right on the floor at each line.

Start Simple, Measure and Adjust Accordingly

This overview is intended to present a broad sampling of tools, standards and methods of performing quality control. Like every new process or piece of equipment, its important to know how the current business is performing in order to understand where to prioritize investment. Starting with something as simple as putting your devices on carts or making a larger commitment to an ISO certification require very different levels of commitment, effort and investment of time and budget.

Wherever you start, it's important to remember that quality control is a continuous process. As soon as you implement one measure, it will be time to look at the next phase of improvement.

Finally, the other overriding consideration in quality control is not as easily measured by a simple ROI calculation. While some investments might not seem worth the marginal benefit, if you are in a highly competitive industry where quality and defect rates can result in disruptions to customer loyalty, it may make sense to look at the bigger picture in collaboration with marketing where reputation and brand value will also play into the decision.

GET IN TOUCH

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ABOUT NEWCASTLE SYSTEMS

Newcastle Systems is committed to providing innovative solutions that help make Auto-ID technology and other hardware truly mobile and information more readily available across an enterprise.

Loss of productivity and inefficiencies such as wasted steps to the printer on a fixed desk, inaccurate inventory counts, improper labeling, time delays, manual processing and incorrect shipments are just some of the challenges that are alleviated with a mobile powered workstation.