

How Manual Inspection Impacts
Critical Component and Medical Device
Manufacturing: Costs, Risks, and the Case for Automation

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Inspection processes are critical in manufacturing to ensure product quality, safety, and compliance with industry standards. Yet for centuries manufacturers have struggled with quality consistency, traditionally relying on manual inspection processes that test the limits of the human eye. But now, with the emergence of Al and its deep learning capabilities, there's the opportunity for automated machine vision systems — running on Al inspection models — to make a big leap in quality control and offer inspection accuracy beyond what has ever been possible before.

This paper is about shining a light on the risks of manual quality inspection, with the **end goal of helping manufacturers achieve the greater product quality that's possible with automated inspection**, as well as the many positive knock-on effects of that outcome streamlined production, less waste, lower costs, a stronger reputation, and higher profits. To accomplish this goal, the paper will cover:

- The Costs Of Manual Inspection Operational, Societal, And Financial
- The Case For A Hybrid Human-machine Approach
- The Benefits Of Automated Inspection And How To Get Started
- Recent Advancements In Machine Vision And How The Technology Is Revolutionising Quality Control
- How Akridata's Unique Technology Helps Manufacturers Establish The Most Accurate Inspection Systems On The Market

The Productivity Costs of Manual Inspection

The repetitive nature of manual inspection is inherently prone to human error, fatigue, and subjectivity, leading to inconsistencies and inaccuracies in quality control. According to research by management consulting firm Kearney, 68% of factory defects are believed to be caused by human error. With such a high figure, it's easy to imagine how even modest reductions in human error could yield enormous benefits for manufacturers.

To look at just one industry example, there were **975** medical device recalls in the United States in 2023, resulting in 283 million recalled units and billions of dollars in financial losses, as well as significant reputation loss. If these negative quality events could be reduced by 68% (or even a fraction of that) with the help of automated inspection, medical device manufacturers and their customers would be markedly happier, healthier, and more prosperous.

Inconsistency and Subjectivity

One of the biggest challenges with manual human inspection is **inconsistency**. The same human inspector can produce variable inspection results from day to day, or even hour to hour, based on their level of mental alertness or fatigue. The acuteness of one's vision can also be a significant factor, with some inspectors catching issues that others with poorer eyesight might miss.

Another common problem with manual inspection is **subjectivity**. Two human inspectors may have differing levels of experience and training, and/or varying interpretations of the company's quality standards. Therefore, a product anomaly flagged as a defect by one inspector could be interpreted as an acceptable cosmetic variation by another.

These inspection inconsistencies and subjectivity issues can result in one of three problematic scenarios:

- Defective products pass inspection and end up in the hands of customers.
- Good products get rejected and end up as unnecessary waste.
- The inspection is inconclusive, potentially resulting in multiple waves of human intervention and a production line bottleneck in order to reach a pass/fail decision.

In all of these scenarios, the result is production inefficiency and potential financial losses for the manufacturer.

Limited Data Collection

An automated inspection system records and remembers the details of every pass/fail decision, including an image of the inspected part, in order to continually learn and improve over time. This data collection and learning process is, however, very difficult to implement and maintain in manual inspection processes.

The speed at which products or parts come off the production line **doesn't allow enough time for human inspectors to record data** about each inspection decision made. In some cases a numerical decision code can be quickly inputted into a device or computer, but without the descriptive context that would allow the decision to be further analysed and understood.

This inherent data gap in manual quality inspection hinders a manufacturer's continuous improvement efforts. Without comprehensive textual or visual inspection data, identifying the trends and root causes of defects becomes challenging.

Scalability Issues

As production volumes increase, scaling manual inspection processes also becomes difficult. **There are limits to human inspection capacity**, and the likelihood of inspection errors increases significantly with the speed, pressure, and fatigue experienced on a busy production line.

Staffing up to meet demand poses its own set of challenges. Besides the costs of bringing on additional headcount, qualified inspectors can be hard to find in certain regions, resulting in employee shortages or lengthy training periods to close knowledge and experience gaps.

The Societal Costs of Manual Inspection

The quality challenges of manual human inspection impact not only internal manufacturing efficiency and productivity, but also the external customer and environmental landscape.

Damage, Injury, and Death

A defective part or product that has inadvertently passed through quality inspection can cause a **ripple effect of harm** after it leaves the factory. A faulty auto part, for example, could lead to an accident that causes damage to vehicles and other property, as well as injury or even death for the individuals involved. Similarly, a medical device with defects could fail to perform its correct function in a critical moment of need, resulting in harmful consequences for the patient.



Waste and Pollution

Beyond the financial waste of manual quality control, there can be **substantial environmental waste** as well. Oftentimes rejected parts or products cannot be reworked or salvaged or it's simply too costly or time-consuming to do so. Therefore, they frequently end up as scrap material, getting destroyed on-site or sent to a landfill.

In the case of product destruction or incineration, these processes require additional energy use and often release harmful fumes into the atmosphere. With landfill dumping, besides contributing to an already troublesome global waste problem, defective parts can create further pollution over time as their materials break down and seep into nearby soil and waterways.

The Financial Costs of Manual Inspection

Not surprisingly, all of these internal productivity costs and external societal costs add up to major financial costs for a manufacturer. Some of those costs are anticipated and easy to see on a balance sheet, while others can be unexpected or less tangible but every bit as significant, if not more so.

Direct Costs

Perhaps the most obvious cost of manual human inspection is labor, as employing qualified quality control (QC) inspectors incurs substantial human resources costs. In the United States, the average salary for a QC inspector now exceeds \$89,000 per year. When that figure is multiplied by the potentially dozens of inspectors needed in order to staff multiple production lines over multiple shifts at a large manufacturing plant, the labor costs very quickly add up. Even in low-cost labor countries where manual inspection may seem economical at \$5-6 per hour, the cumulative costs of errors including rework, scrap, and customer dissatisfaction can far outweigh these savings.

Inspectors also need **training and certification**, both upon their hire and on an ongoing basis in order to stay current with required industry standards as well as changing company quality policies. This requirement, along with the ~40% of annual attrition in manufacturing companies, further adds to the recurring operational expenses of manual inspection.



\$89K/Year
Average U.S. QC
Inspector Salary



Dozens Per Shift

Large Plants Require

Multiple Inspectors



40% Attrition
High Turnover Increases
Hiring & Training Costs



Ongoing Training
Certification & Compliance
Add Recurring Costs

Indirect Costs

Manual inspections are slower in general and can create **production bottlenecks and delays**, particularly when a pass/fail decision isn't obvious and the product or part requires further inspection. These delays reduce production output and increase time-to-market, and can potentially result in missed market opportunities and a diminished level of competitiveness for the manufacturer.

Beyond the challenges of speed, small manual inspection errors often result in defective products slipping through the cracks and reaching later stages of the production cycle. This can produce additional indirect costs in a number of ways:



Manual rework to bring the part or product back up to acceptable standards.



Energy use and manpower to process and dispose of unusable scrap materials.



Significant losses and resources required to issue a **product** recall.

Considering that <u>human inspectors successfully identify only about 85% of defects on average</u>, indirect costs such as those outlined above are surprisingly common. With a 15% error rate, product defects quickly escalate into substantial costs for manufacturers. Plus, as production volumes increase, it becomes increasingly difficult to maintain the necessary throughput and accuracy with a purely human-driven inspection process.

Hidden Costs

Undetected defects due to manual inspection errors can also lead to a number of hidden costs that may cause serious financial and legal harm for a manufacturing company. For example, in high-stakes, heavily-regulated industries like medical device manufacturing, **Product Compliance Violations** often result in steep fines, legal challenges, and even the suspension or revocation of critical business licenses.

In the aforementioned case of a product recall, a manufacturer not only faces the immediate time, effort, and monetary expenditures of the recall exercise itself, but also the **Long-term reputation damage** that commonly results. Product recalls and other quality issues stemming from manual inspection failures can cause irreparable damage to a manufacturer's brand reputation permanently eroding customer trust, company market share, and future revenue potential.

The New Role of Humans in the Quality Loop

Do all of the above cost, risk, and efficiency challenges mean that humans should be removed altogether from the quality control process? Absolutely not. Manual inspection remains a key element of the quality control loop in most manufacturing sectors, including medical devices and critical components (e.g., auto parts). However, the role of humans is now changing.

Under automated machine inspection, the human role shifts from inspector to arbitrator. Instead of performing each inspection themselves exposing the quality control process to the inevitable inaccuracies that accompany the manual approach human inspectors move off to the side and serve as "tier-two" quality agents. When the outcome of machine inspection is uncertain for a part or product, or does not meet an elected confidence threshold, the human inspector intervenes to arbitrate the decision and make the final call.

While automated systems excel at quickly detecting the most common, easily measurable defects such as size, weight, or shape differences, human judgment is often needed to assess the less common but more subjective criteria, like minor blemishes or color discrepancies that can be purely cosmetic in nature and may not be deemed unacceptable. Therefore, this augmented, hybrid approach offers the best of both worlds.

Automated Inspection: The Competitive Edge of Quality Control

With the accuracy and accessibility of Al-based machine vision technology today (discussed further in the next section), significant quality improvement has never been more achievable for manufacturers. By implementing an intelligent, hybrid inspection approach one that relies on automation and leverages human inspectors more strategically as needed manufacturers can expect to realize many benefits.

Enhanced Accuracy and Consistency

Automated inspection systems utilize advanced technologies such as AI and machine vision to detect defects with **higher accuracy** and consistency than manual methods. AI-powered visual inspection systems excel in identifying subtle defects that might be overlooked by human inspectors, ensuring adherence to strict quality standards. These systems also provide consistent results, significantly reducing the variability associated with manual inspections and enabling manufacturers to maintain a higher level of quality assurance in their production processes.

Therefore, a hybrid human-machine inspection process outsources the majority of the inspection task to a vision system that's been trained to detect the most common defects with extremely high accuracy, and reserves human inspection only for the less frequent situations that truly need it. This approach leads to improved product quality and reduced error rates for manufacturers.

Increased Throughput and Scale

As discussed earlier in the paper, human inspectors have productivity limits. When production speed increases, so do the stress and fatigue levels of the employees working on the production line. Plus, a manufacturer's attempts to increase speed and throughput often backfire in manual inspection environments, as the inevitable drop in inspection accuracy only creates more waste, rework, and risk for the business.

Automated inspection, on the other hand, has far fewer productivity limits. It can easily handle higher speeds, allowing manufacturers to accelerate the inspection process and increase throughput without compromising quality. Automation also scales across production lines, and across manufacturing facilities, more easily and cost-effectively than human inspection processes. The result for manufacturers is an overall jump in production efficiency and flexibility that helps them more effectively meet market demands.

Cost Reduction

Implementing automated inspection systems can significantly reduce a manufacturer's reliance on manual labor, particularly for repetitive tasks, thereby lowering labor costs and payroll expenses. Automation enables manufacturers to hire fewer QC inspectors, and have fewer on-site at once, as their new defect arbitration role requires less hands-on time and allows them to cover multiple production lines simultaneously.

While the initial investment in automation technology may be significant as is the case with any physical production line upgrade the long term cost savings are substantial. Automated inspection systems can operate continuously, reducing the need for breaks and minimizing the risk of human error. This efficiency improvement lowers production costs and creates a higher return on investment over time.

Improved Data Collection & Analysis

Automated vision systems automatically collect comprehensive data during the inspection process, facilitating **advanced analytics and continuous improvement initiatives.**Additionally, QC inspectors now have time to capture and record more data about each manual inspection they conduct, and to take on a more strategic role in the plant for example, by performing root cause analysis on their observed inspection patterns to improve various steps of the manufacturing process. This hybrid, data-driven approach enables manufacturers to quickly identify defect patterns and implement corrective actions much sooner than would be possible with manual inspection alone.

The Time is Now: Recent Advancements in AI & Machine Vision

While the downsides of manual only inspection are clear, switching to a heavy reliance on machine inspection for quality control only makes sense if the technology is sophisticated enough to excel at the task. For years, that wasn't necessarily the case. Today, however with significant recent advancements in Al and machine vision practices it most certainly is

Al Evolution

The **significant strides made in artificial intelligence technology** over the past few years have been instrumental to bridging the gap between subjective human inspection and precise automated inspection. Similar to the evolution seen in popular Al models like ChatGPT, **Al-enabled machine vision systems are now fully capable of understanding complex visual patterns** and making decisions that were once reserved for human inspectors.

This progress has been made possible by the development of foundational models that can learn from large, diverse datasets and continually improve over time.

Enhanced Model Training

A major shift in machine vision technology is the rise of deep learning (DL) models, which have surpassed classical computer vision approaches' ability to recognize patterns and make decisions. Unlike traditional methods that rely on predefined rules and feature extraction, DL models leverage neural networks trained on vast amounts of data, requiring significant computational power, often provided by GPUs.

These **sophisticated custom models are able to account for previously unattainable variables** such as factory lighting conditions, camera angles, and production line layouts — all critical elements for ensuring that automated inspection systems can function with maximum levels of accuracy in real-world manufacturing environments. Such custom vision models are what are now allowing manufacturers to eliminate the inherent inconsistency and subjectivity of manual quality inspection.

Accurate machine inspection involves collecting and processing many hundreds of thousands of images in order to train the custom vision model, and to help it further improve over time with fresh inspection imagery every day. These processes involve significant computational power that previously wasn't within reach for most manufacturers, or at least not at an attractive price point. This, too, has now changed.

Technological advancements with Graphics Processing Units (GPUs) have enabled greater computational power and speed at a more affordable price, making it now possible to deploy cutting-edge, cost-effective machine vision systems that provide significant savings over manual-only inspection. Additionally, the improved processing power has made it possible for Al to start assisting in subjective decision-making tasks, such as distinguishing acceptable minor blemishes from unacceptable defects, with little to no human intervention.

Industry Spotlights

The medical device industry is subject to stringent regulatory standards that require high inspection accuracy to ensure product safety and efficacy. Non-compliance can lead to severe penalties and even market withdrawal. But automation in medical device manufacturing has been shown to increase inspection accuracy and enhance production efficiency, leading to as much as a 50% decrease in production costs.

Automotive manufacturing is another good example of a critical components industry that's leading the adoption of automated inspection solutions. As with medical devices, compliance with strict regulatory and safety standards is paramount when manufacturing vehicle parts in order to ensure customer safety and business continuity.

Medical Device Manufacturing

Defects in the medical device industry can have severe consequences, including **risks to patient safety and significant financial liabilities**. The U.S. Food and Drug Administration (FDA) emphasizes that defects or performance failures of marketed medical devices can **pose serious risks to public health**, leading to recalls to correct or remove defective products. Recent examples of this include **Johnson & Johnson's paused rollout of its Varipulse heart device** due to patient health complications, and **Philips Respironics' recall of certain breathing assistance machines** due to device quality issues.

Automotive Component Manufacturing

Recalls are now a common occurrence in the automotive industry. In fact, more than 27 million vehicles have been recalled in the United States every year for the past three years due to defective components. As vehicles are becoming more and more complex to manufacture and inspect containing an ever-increasing number of electronic components to support autonomous capabilities and other smart features this trend will only continue without significantly enhanced quality control and inspection measures in the industry.

Recent quality incidents include Ford's recall of nearly 1.89 million vehicles due to an issue with the vehicles' A-pillar components, and Tesla's recall of 239,000 vehicles due to a rear-view camera issue. Such incidents emphasize the critical importance of rigorous, automated inspection processes to prevent automotive component defects. When defective parts or vehicles reach the consumer marketplace, they can lead to accidents, legal liabilities, and substantial financial losses amounting to many millions (or even billions) of dollars, plus the associated damage to a manufacturer's brand reputation.

Overcoming the Barriers to Automation Adoption

Shifting quality control processes to an automation-led approach can feel like a daunting task for manufacturers. While the benefits of automated inspection systems are clear, adoption in critical component and medical device manufacturing often faces significant barriers. However, as is the case with many meaningful upgrades to a manufacturing process, there are ways to lower those barriers and ease the automation journey with a measured approach.

Start With a Proof of Concept

A primary hurdle for manufacturers is the challenge of demonstrating the technology's effectiveness. Rightly so, manufacturers require robust evidence that automation will deliver meaningful cost savings and quality improvements for their operation before investing in a full roll-out. This is why it's key to first establish a structured and well-defined proof of concept (POC).

To test, refine, and analyze the performance of an automated inspection process, it is recommended to start with one part or product, on one production line, in one manufacturing facility. Ideally the component chosen for the POC should be one that's particularly labor-intensive to inspect manually, and/or has lower than average quality scores.

Once the above parameters have been defined for the POC, the next step is to deploy calibration hardware to the selected production line. Some manufacturers may have existing image datasets and/or imaging technology in place that could be utilized for the calibration process as well. In most cases, however, the manufacturer will need to install temporary inspection stations on the line. These specialized hardware systems will scan the components and collect extensive image data over the course of several weeks. This data then serves as the crucial foundation for effectively training the custom Al vision model.

Leverage Existing Data

With the POC framework and hardware systems in place, the next step is to properly train the custom AI model to distinguish between acceptable and defective components. This process requires large volumes of labeled images, and the image data collected from the POC's hardware systems and/or existing image databases may not be sufficient on its own to achieve the desired levels of inspection accuracy.

To overcome this challenge, innovative automation partners are meeting manufacturers where they are by **leveraging pre-existing computer vision data from a variety of open sources**. The right vendor will be able to repurpose **publicly available** images collected for other inspection purposes, coupled with POC hardware imagery, to begin training the Al model.

Another smart technique for getting started with machine vision model development is using advanced AI co-pilots for image classification. Like intelligent virtual assistants, these AI co-pilots assist in the initial stages by separating images into "good" and "bad" categories. This process accelerates the creation of a reliable model and reduces the heavy data burden on manufacturers.

Scale at the Pace of Success

While it's tempting to try to reap the many benefits of automated inspection as quickly as possible, the transition to automation should be viewed as more of a marathon than a sprint. Rushing a machine vision implementation, or scaling it to other environments before the model has been properly trained and fine-tuned, can yield just as many defect detection errors as manual inspection, thus negating the benefits.

The time it takes to experience the quality improvements of automated inspection can vary widely from one manufacturer to the next. For relatively simple products or parts, a highly accurate vision model can be developed in just a matter of weeks. For more complex components, several months can be required to fine-tune the vision model to the point of high inspection confidence and self-sufficiency.

When starting the automation journey, it's important to have patience and to scale the initiative in a measured fashion as performance targets are reached. Incorporating some time flexibility into the process is a good thing, as well-trained Al vision models only get better over time, not worse.

AKRIDATA'S IMPACT Redefining Automated Inspection Excellence

A vision system that's been improperly trained will be no more efficient than manual inspection. That's why, since 2018, Akridata has focused on becoming the leading experts in high-accuracy AI machine vision modeling for complex manufacturing environments.

Akridata Inspection Studio

Our <u>Inspection Studio</u> data platform serves as a <u>crucial intelligence layer to help manufacturers make better inspection</u> decisions. The platform uses deep learning to accurately classify component imagery in order to maximize production yields and minimize defective shipments increasing product quality, driving down operational costs, and reducing the impact of defective products.

The Akridata Difference

Other machine vision platforms exist in the marketplace, but what makes Akridata's approach stand out?

____ Detail



Akridata's deep learning Al models and batch-based analysis allow Inspection Studio to detect even the most subtle variations in device construction, catching defects that other solutions miss, and doing so much earlier in the production process.



Context

In addition to providing pass/fail data, Akridata goes the extra mile to explain why each decision was made. Analyzing this contextual decision data helps clients identify the root cause of defects and implement corrective measures.



Flexibility

Akridata's modular approach to automated inspection works with all imaging hardware systems, can be customized to meet the needs of any manufacturing environment, and easily scales across multiple production lines and facilities.



Compliance

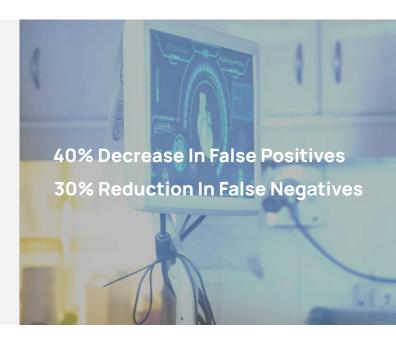
Akridata proactively helps manufacturers maintain compliance with regulatory standards by providing detailed inspection records. In the event of an audit, clients can easily pull auditable reports and tear sheets from the platform.

Case Studies

Akridata is helping manufacturers from a wide range of industries improve their quality control processes to conserve costs and increase profitability. Here are just a few recent examples:

A large medical device manufacturer came to Akridata wanting to improve the accuracy and efficiency of its computer vision based inspection lines. The company's existing system fell short, despite repeated model tuning. Real-world production conditions and a rigid, speed focused approach caused incorrect part flagging, posing the challenge of maintaining speed without sacrificing accuracy or risking defective product shipments.

Leveraging Akridata Inspection Studio, the manufacturer achieved a 40% decrease in false positives and a 30% reduction in false negatives, significantly reducing inventory wastage and safeguarding the brand's esteemed reputation.





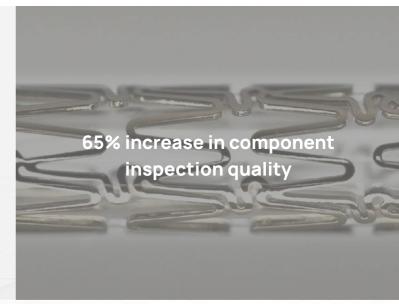
A transducer manufacturer used in electronic devices was relying on manual human inspection for quality control, taking about 60 seconds per component.

By implementing Akridata Powered machine vision technology, the company was able to reduce the inspection time per component down to 10 seconds a **6X improvement in throughput** with even greater speed possible upon further expanding the system.

At the same time, the manufacturer successfully **decreased false negatives from 7.3% to 1.5%**, reducing unnecessary component waste, and **lowered the required inspection labor from 16 inspectors per shift to 4**.

Another large medical device manufacturer making heart stents compared their standard microscope-based manual inspection process to a hybrid human-machine inspection process employing Akridata.

With the machine vision system handling the core inspection task, and the human inspectors focused solely on arbitrating any inconclusive image results flagged by the system, the manufacturer's inspection quality for this component increased by 65%.





Whether you're considering automated inspection for the first time, or looking to improve upon existing initiatives, hopefully, this paper has helped inspire the next step in your quality improvement journey. To recap the key points of the paper:

Costs of Manual Inspection: Human-only quality inspection suffers from inconsistency and inaccuracy. It reduces a manufacturer's operational efficiency, creates consumer risk and environmental waste, and incurs significant labor, rework, and recall costs.

New Role of Human Inspectors: Despite the challenges of manual inspection, human QC personnel are very much still needed on the factory floor. However, their role is now shifting from inspector to arbitrator serving as "tier-two" quality agents to make the final call when a machine inspection is inconclusive.

Benefits of Automated Inspection: Using a highly-trained AI model that gets better and better over time, the benefits of machine inspection are clear to see greater accuracy and consistency, increased throughput and scale, better data collection and improvement opportunities, and lower operational costs for the business.

Technological Readiness: With recent advancements in AI sophistication, machine vision methods, and computational power, automated inspection technology has reached the point of being both accurate and affordable enough to significantly outperform manual inspection in manufacturing environments.

Overcoming Automation Barriers: To ease the process of getting started with automated inspection, start with a clear proof of concept initiative with a limited, focused scope. Work with a machine vision partner who's able to leverage a variety of image datasets to more quickly and thoroughly train the Al inspection model, and scale the process to other environments mindfully as success metrics are reached.

While it can feel daunting to start, the benefits of automated inspection soon greatly outweigh the implementation logistics and costs. By deploying a highly detailed and flexible inspection platform such as Akridata Inspection Studio, quality control can go from being a manufacturer's weakness to becoming a core strength.

To discuss how automated inspection can move the quality needle in your specific manufacturing environment **book a consultation** with our team today.