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Closing the QA Gap: Why Medical Device OEMs Must Shift Quality Upstream

Executive Summary

- Despite known compliance and reputational risks — and **the FDA's ever-growing database** of product recalls — quality assurance (QA) in the medical device supply chain remains an end-of-line afterthought.
- But when device defects are caught only after sterilization and shipment, both original equipment manufacturers (OEMs) and contract manufacturers (CMs) take a financial hit via rework, lost time, and damaged trust. This downstream QA model no longer holds up.
- Shifting QA inspection upstream protects margins, improves throughput, and strengthens manufacturing relationships. With AI-powered visual inspection and traceable QA data, OEMs and CMs align on shared quality thresholds, catch defects earlier, and avoid costly batch rejections — all without disrupting production flow.
- If you're an OEM or CM feeling current processes lack behind quality standards, thinning margins, and rising batch rejection risks, it's time to rethink where QA should begin.

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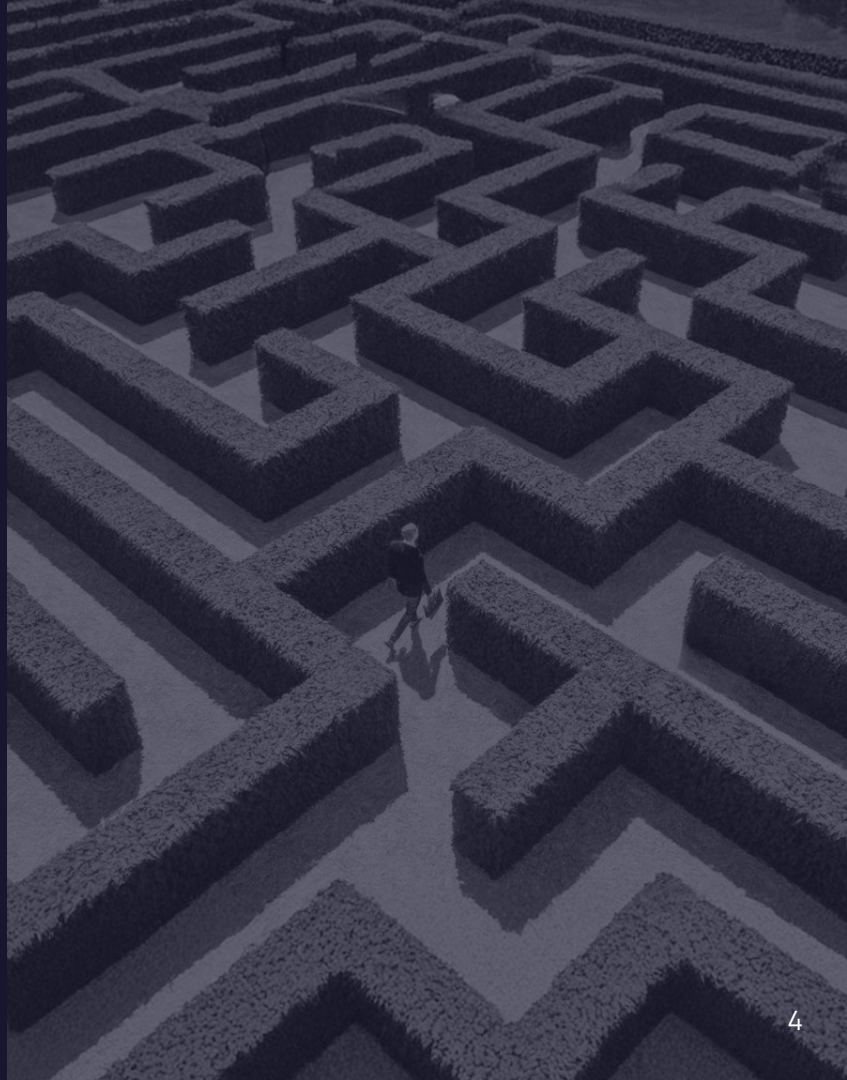
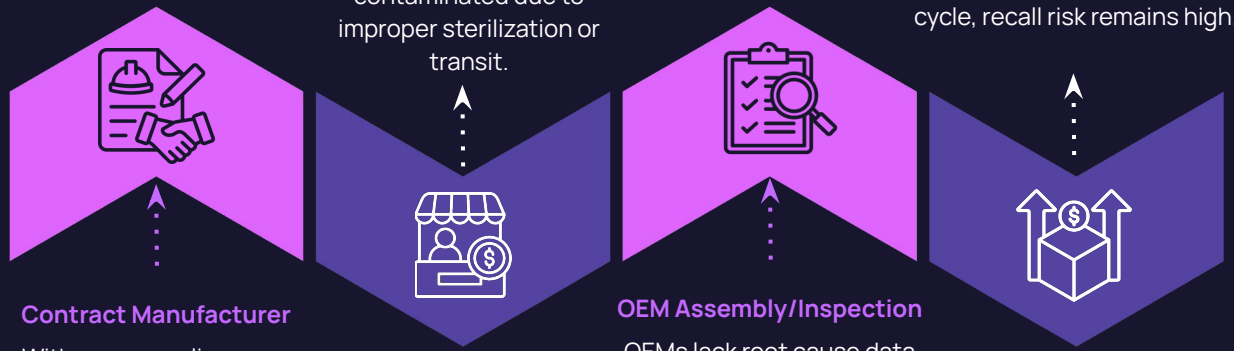


The Hidden Risks in Downstream QA

- Today's standard medical device manufacturing workflow puts quality assurance at the end of the line. With a lack of clear acceptance thresholds, production controls, and defect traceability embedded throughout the process, CMs and OEMs regularly face costly rejections, rework, and delays.



Contract Manufacturer

With an over-reliance on manual quality inspection, CMs can often miss defects.

Sterilization Vendor

Clean devices can become contaminated due to improper sterilization or transit.

OEM Assembly/Inspection

OEMs lack root cause data for issues found, and can incur hefty rework costs and delays.

Market Release

With detailed inspections happening so late in the cycle, recall risk remains high.

What's at Stake for OEMs & CMs

- Delaying QA — and having to reject a batch of components or devices post-sterilization — creates unforeseen costs for OEMs and CMs.

- **Financial Costs:**
  A single rejected batch can cost $600K - $2M+ in logistics, rework, and re-sterilization fees.

- **Timeline Costs:**
  Late rejections delay product availability by 2-4 weeks, on average.

- **Reputational Costs:**
  Experiencing repeated QA issues is among the top 3 reasons why OEMs choose to switch to a new CM.

> In June 2021,
> Philips Respironics recalled
>
> **15 million**
>
> breathing apparatus machines due to device quality issues.[1]

Sources: [1]FDA Recall Incident Report

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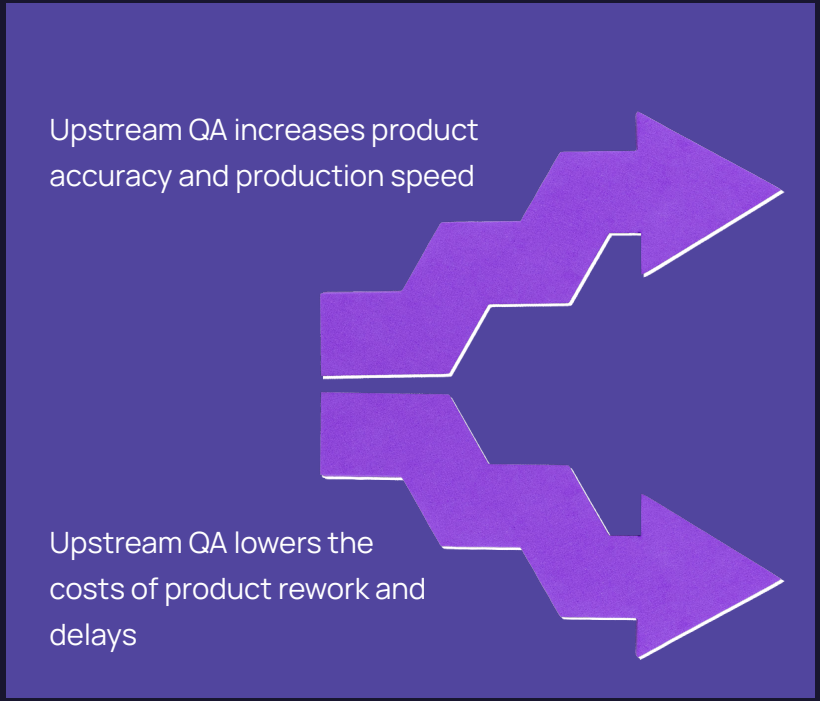
Opportunities

- Why QA Needs to Move Upstream
- Rethinking the OEM-CM Relationship

Why QA Needs to Move Upstream

- QA and compliance challenges are a top cause of product launch delays for medical device manufacturers. However, by shifting quality checks closer to the point of assembly, several critical benefits surface:
  - **CMs** are able to more proactively detect and prevent issues before shipping any devices or components out the door.
  - **OEMs** gain greater confidence in device quality and compliance, with less worry of overloading inbound QA teams.
  - **Both parties** are able to dramatically reduce the costs of manual rework and re-sterilization downstream.



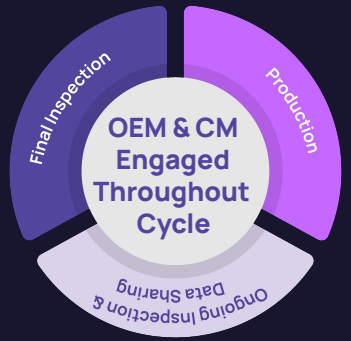
Rethinking the OEM-CM Relationship

- Upstream QA isn't just about saving money or avoiding reputational harm. It also creates mutual accountability for OEMs and CMs — as well as stronger, longer-lasting partnerships.

Old Model

OEMs inspect finished components and enforce their standards, despite CMs often lacking full visibility into final acceptance thresholds. Correction costs fall mainly on the CM.

New Model



OEMs and CMs align on shared QA standards, methods, and data. Inspection occurs throughout the production process, with both parties taking ownership over any add-on QA costs.

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Method

- AI-Powered Inspection Enables the Shift
- Creating a Traceable QA Chain
- Upstream QA in Action

AI-Powered Inspection Enables the Shift

AI visual inspection removes the bottlenecks and subjectivity of manual inspection.

Accuracy
Greater Inspection Confidence

- **Detail:** Machine vision systems are able to detect very small anomalies and defects that humans can miss, eliminating variability among operators.
- **Scale:** AI systems do not fatigue, allowing for higher throughput without compromising quality.

Optimization
Better Site-to-Site Performance

- **Locations:** The AI inspection process standardizes inspection criteria and execution across sites.
- **Labor:** Human QA inspectors can focus on higher-value quality improvement initiatives.

Learning
Continuous Improvement Over Time

- **Growth:** AI inspection models continue to learn as they're running, getting better with every batch.
- **Correction:** Detailed inspection data facilitates root cause analysis to correct production gaps or flaws.

Fewer product quality surprises, more on-time product deliveries

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Creating a Traceable QA Chain

The many benefits of automated inspection & data logging:

Shared Data Visibility
Promotes greater transparency and defensibility

Clear Traceability
Easily identify the themes and causes of defects

Faster Reaction Times
Address quality issues as they arise, not after the fact

Inspection Analytics
Track performance over time to monitor QA progress

Regulatory Readiness
Clear, audit-ready record keeping and documentation

- One of the many significant flaws inherent in manual inspection processes is the lack of detailed inspection logs. This not only hinders a manufacturer's ability to detect and react to QA patterns, but it also creates complexity and risk in the event of an audit.
- AI-powered inspection creates a clear, traceable QA chain logging inspection history, imagery, and decision rationale. This process puts OEMs and CMs on the same page, allowing them to react quickly to production issues and saving hundreds of hours of regulatory work for compliance reporting and audit readiness.

Upstream QA in Action

Situation

A CM making catheters installs AI inspection at the final assembly point. Catheters are inspected to ensure they have the required microscopic holes at the tip, and a recurring blemish is detected.

Results

- **Speed:** Defect was removed immediately in-line before packaging, preserving throughput and eliminating delays.
- **Savings:** OEM received a clean device batch, with no re-sterilization or re-labeling costs.
- **Relationship:** CM retained the OEM's trust thanks to proactive AI inspection vs. allowing the defect to be caught during final QA.

An AI vision system inspection image of a catheter tip, assessing the placement and integrity of the required holes.

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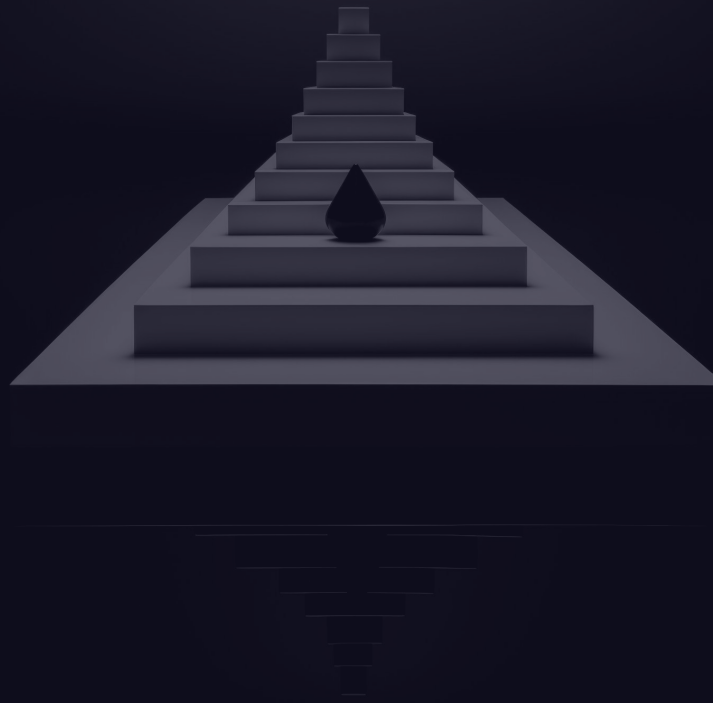
Roadmap

- Getting to Upstream QA
- How Akridata Helps
- Final Takeaways



Getting to Upstream QA

01 **Map your current QA workflow.** Lay out the existing process end-to-end, and highlight where manual inspection currently takes place.

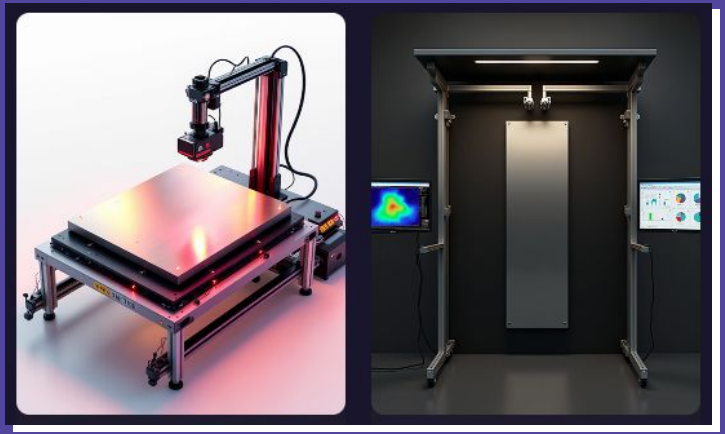
02 **Identify failure points.** Examine your history of component QA data to determine where quality issues typically surface.

03 **Deploy AI-powered inspection.** Work with a tech partner to place a vision system immediately after your most common or problematic failure point, or at final assembly.

04 **Define shared pass/fail logic.** Connect with your CM or OEM to agree upon the criteria for an acceptable component, and what constitutes a defect.

05 **Pilot, iterate, scale.** Establish a well-defined proof of concept for one component, on one line, in one facility — expand from there as performance targets are met.

How Akridata Helps



Akridata's Vision Assist, Vision Command, and Vision Copilot systems combine customizable, in-line image capturing technology with AI models for highly accurate defect detection.

- Akridata — an experienced industry leader in AI-powered visual inspection — helps OEMs and CMs align on quality before it becomes a problem. We fully support your upstream QA transformation with:
- Modular AI inspection models built to catch the anomalies humans miss.
- Lightweight vision system deployments on CM production lines.
- Shared QA dashboards with quality thresholds and real-time performance.
- Secure, auditable logs for regulatory readiness and confidence.

Final Takeaways

01 **Downstream QA is too reactive, and too expensive.** Get proactive with your quality inspection — reduce unnecessary rejections and delays by moving QA upstream.

02 **AI visual inspection is faster and more consistent.** It also protects margins for OEMs and CMs by optimizing QA labor and avoiding rework, re-sterilization, and recalls.

03 **Upstream QA strengthens OEM-CM collaboration.** It improves transparency and helps both parties work together under shared QA processes, standards, and data.

04 **Akridata enables the shift.** Our technology is built to handle complex medical device workflows, and can be customized to suit any component and production line.

Get in touch with our inspection experts today

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Smarter Visual Data, Better Human Decisions.

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