

Quality Excellence in 2026

Navigating Critical Trends in
Pharma and Medical Device
Quality Management





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MasterControl

1100+

**Organizations Use MasterControl
Quality Management Solutions**

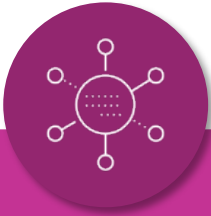
2026 Outlook

**Key Commonalities Across Medical Device and
Pharmaceutical Operations**

- **The Stakes Are Higher: 41% increase in FDA warning letters**
- **Regulatory Convergence: Similar expectations emerging across pharma and devices**
- **Digital Transformation is Now: No longer future concept but operational reality**
- **From Silos to Systems: Success requires connected quality ecosystem**
- **The New Baseline: What was cutting-edge is now minimum requirement**



Overall Life Science Trends



**AI-Powered
Quality
Management**



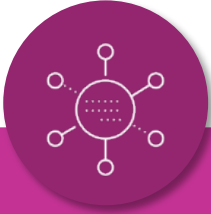
**The CSV to CSA
Validation Shift**



**Remote
Regulatory
Assessments**



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From “What If?” to “What Now?”

Regulatory Impact



- Regulators are governing AI
 - EU AI Act
- Regulators are using AI
 - ELSA and Agentic Programs

Organization Governance



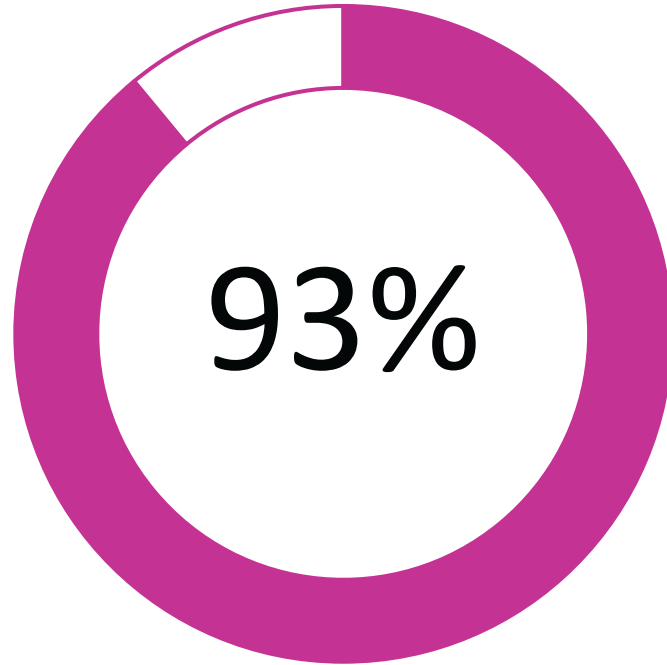
- Human in the Loop
 - Control for compliance
- Frameworks
 - Define use cases, update SOPs, understand risk



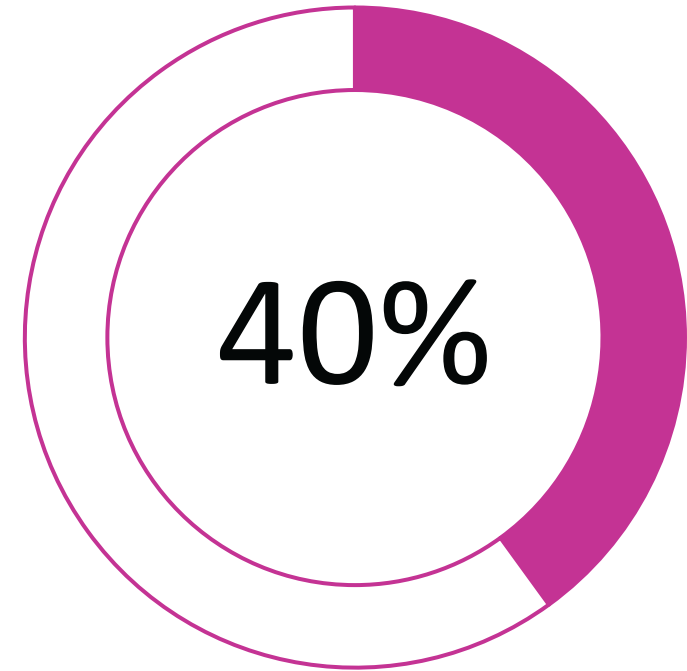


GenAI Has Quickly Become a Top Priority

Executives who view AI as an instrument of cost reduction



Projected efficiency gains for companies using GenAI





But Adoption is Still in the Early Stages

90%

of organizations are still in the earliest stages of AI adoption

2/3

Know the areas where they want to prioritize AI, but do not have an implementation plan

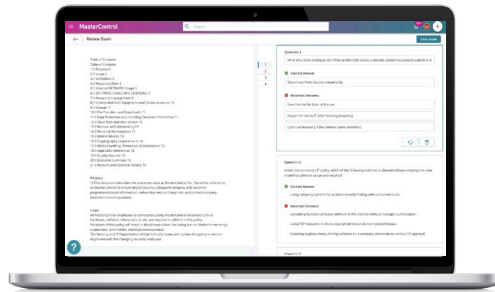
6%

of companies have upskilled workers on AI

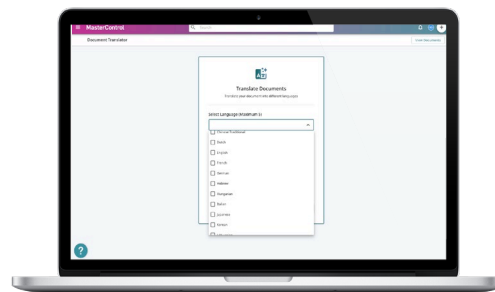


From “What If?” to “What Now?”

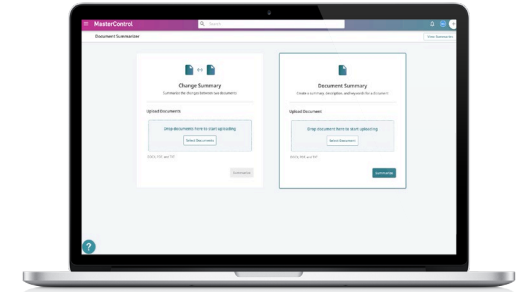
AI-Powered Quality Management



Exam Generator



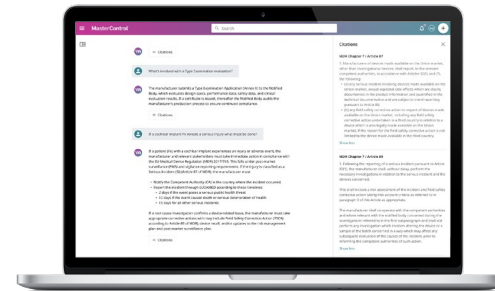
Document Translator



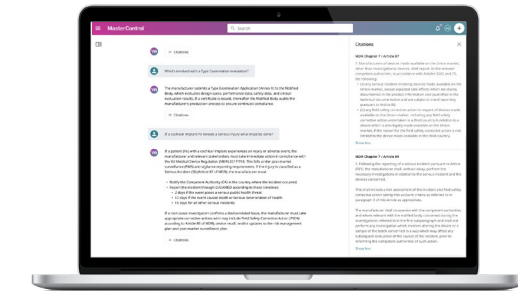
Document Summarizer



Training Slippage Predictor



Regulatory Chat



SOP Analyzer



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**The CSV to CSA
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FDA's Computer Software Assurance (CSA) elevates a **risk-based approach** emphasizing **“fit for intended use,”** moving away from prescriptive CSV heavy scripting.



Leaner and Cleaner Validation

Vendor Validation

Strong vendor-provided materials, such as risk assessments for core system functions and template guidance for testing higher-risk features like electronic signatures or audit trails, allow manufacturers to use vendor evidence, certifications, and service agreements as part of their validation process.

Accelerated Deployment

CSA bridges the gap between the agile nature of SaaS (with frequent updates) and the need for re-validation, enabling manufacturers to adopt new features more quickly through a streamlined assurance process.



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The "Inspection Anytime" Reality



01.

Virtual Audit Room

Create a secure, controlled digital environment to provide auditors with time-bound, least-privilege access to relevant documentation.

02.

Embedded Preparedness

Integrate procedures for managing remote record sharing and virtual walkthroughs into your standard quality management system.

03.

Link Findings to CAPAs

Ensure that any findings from a remote assessment are immediately linked to your internal CAPA and retraining processes, with a full audit trail to demonstrate closure.



Industry-Specific Trends

Pharma

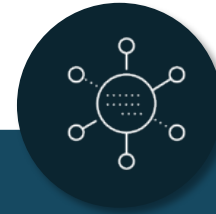
Med Dev



**Supply Chain
Quality**



**Regulatory
Harmonization**



**Cyber-
Security**



Industry-Specific Trends

Pharma

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**Supply Chain
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Connected and Resilient

01.

DSCSA

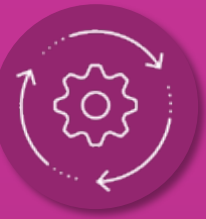
Regulators are raising expectations for supplier quality oversight and timely incident response with full enforcement of the Drug Supply Chain Security Act (DSCSA).



02.

Supplier Connectivity

Quality leaders will need to demonstrate control from supplier to patient.





Global Alignment

01.

ICH/IPRP Momentum

Ongoing convergence via ICH, IPRP, PIC/S, and ICMRA reduces regional divergence and encourages consistent global quality processes.



02.

Consistency

Less duplication across regions but higher expectation for data transparency and cross-site process consistency.





Industry-Specific Trends

Pharma

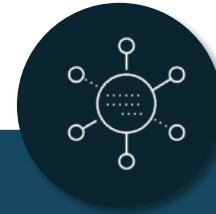
Med Dev



Supply Chain
Quality



Regulatory
Harmonization



Device Security
and PCCP



Global Alignment

01.

QMSR

QMSR harmonizes U.S. regulations with a global standard AND it retains key FDA-specific requirements, creating a hybrid model.



02.

Audit Changes

Risk management as a central, integrated process rather than a siloed activity.





Secure and Compliant

01.

SBOM/VEX

Providing a software bill of materials (SBOM) is a standard requirement for premarket submissions.



02.

PCCP

The FDA's Predetermined Change Control Plan (PCCP) guidance becomes a critical framework for innovation and compliance.



DATA

An underlying force in all coming trends.



Data Harmonization First, AI Second

01.

Data Governance

AI is only as reliable as the data it learns from. By ensuring data is accurate, structured, consistent, and compliant with regulatory expectations, organizations can confidently deploy AI to improve quality, accelerate decisions, and enable automation.

Without strong governance, AI models introduce risk rather than value—making governance the critical first step toward safe, scalable AI adoption.



02.

Data Connectivity

Recognizing gaps in data readiness is crucial for life sciences operations to reliably use AI in their GMP environments.

Removing silos, connecting data for interoperability across critical operations—quality events, batch records, supplier information, audit records, etc.



A Data-Centric Approach

“

A lot of the times, organizations make the mistake of doing AI without paying attention to data, and they soon find out that they should have started with the data side to really develop a robust strategy.

– Chief Data & Analytics Officer, Biopharma

77%

of life sciences leaders say they've either already adjusted or plan to overhaul their data strategies.

Lack of Insight Across Processes Drive AI Limitations

71%

**Of AI implementation status
is still in pilot phase
according to research
respondents**

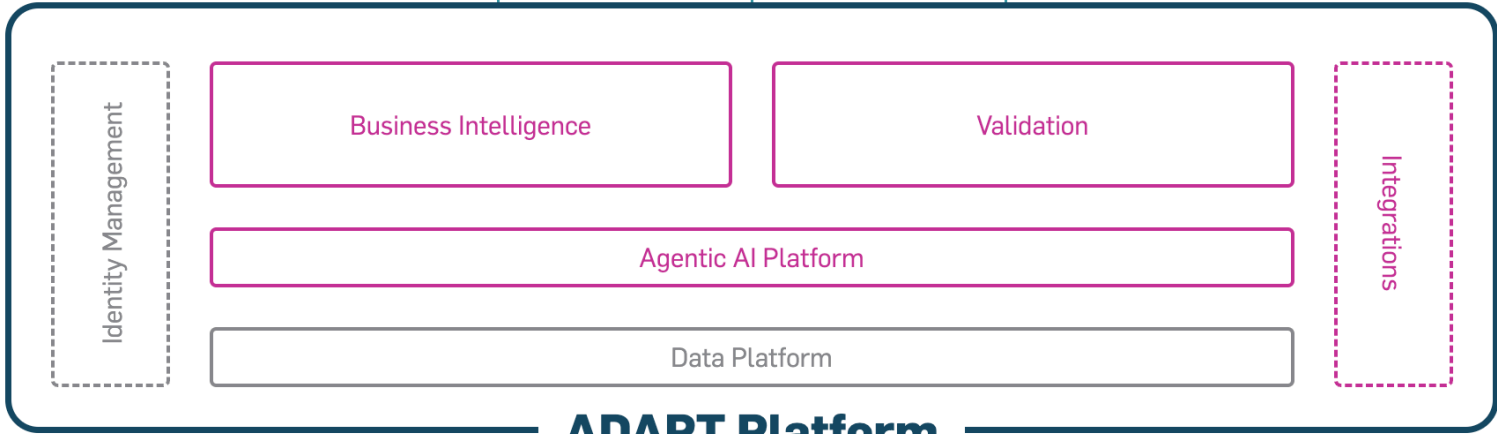
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"In our industry, whether it's pharma, medical device, biologics, we're very cautious, especially around tools that take away transparency or decision-making capabilities, right, so the mantra in the industry typically is trust but verify and so, I think we're very slow to adopt AI."

Qx
Quality

Mx
Manufacturing

Ax
Asset





The Clear Leader: AI Compliance

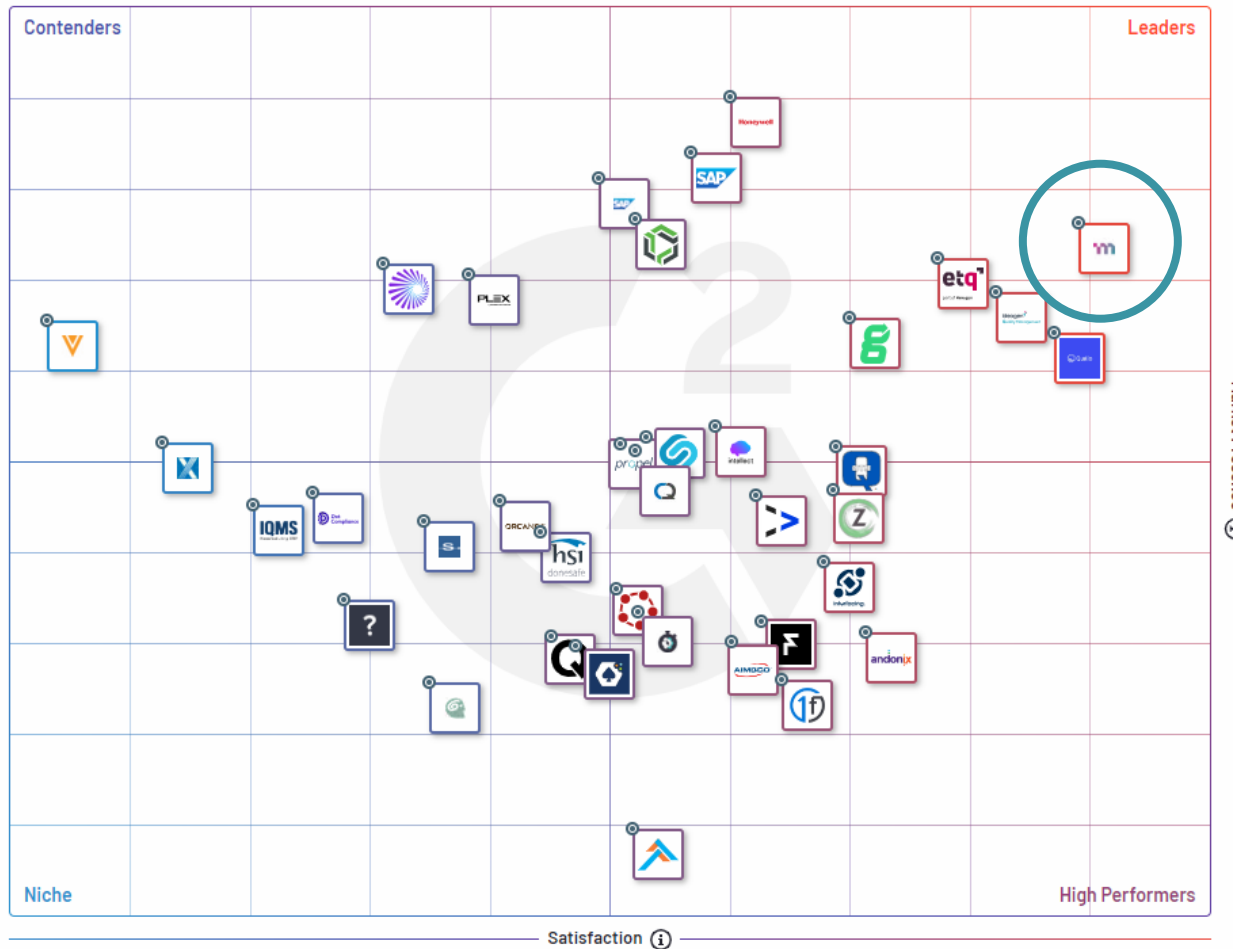


- **MasterControl achieved ISO 42001 Certification in July 2025, one of only 50 global companies. This demonstrates our:**
- **ETHICAL APPROACH:** Commitment to building ethical and reliable AI technologies that are trustworthy and that maintain human oversight and data integrity.
- **SPECIALIZED ARCHITECTURE:** Provides assurance that our AI implementations align with evolving regulatory expectations in life sciences and manufacturing, helping you maintain compliance while benefiting from advanced AI capabilities.

The Clear Leader



Qx - Quality Management System (QMS) Software Products



G2 Grid® Scoring



MasterControl is the life sciences industry's #1 QMS



- 30 Years of Leadership
- History of Innovation
- Connected Quality, Manufacturing, and Asset Management

POLL

**Which coming trend will most impact your
quality teams in 2026?**

Q&A





Thank You!

