

Magic Quadrant for Quality Management System Software

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Quality leaders face challenges evaluating QMS software due to market saturation, industry-specific feature sets and broad platforms that may overlook core quality needs. This Magic Quadrant compares key vendors to aid organizations in selecting the right solution.

Market Definition/Description

Gartner defines the market for quality management system (QMS/eQMS) software as stand-alone digital solutions with embedded emerging technological capabilities that enable organizations to systematically manage, monitor and improve the quality of their products, processes and services. These software solutions help organizations meet customer quality expectations and maintain compliance with international standards as well as industry-specific regulations.

QMS software is designed to help organizations reduce waste, lower costs, house quality documents, assess risk, track performance, ensure compliance and improve processes. The QMS/eQMS market serves a broad spectrum of industries, including manufacturing, life sciences, automotive, aerospace and defense, electronics, food and beverage, chemicals, consumer packaged goods, services, and more. These solutions are built to help organizations of all sizes, from single facilities to complex, global operations, establish a consistent approach to managing and enhancing the quality of products, processes and services throughout the value chain.

Mandatory Features

For a platform to be considered a QMS/eQMS, it must maintain compliance with international standards such as ISO 9001, as well as industry-specific regulations such as those from the U.S. Food and Drug Administration (FDA) and the Federal Acquisition Regulation (FAR). The system must also have the following functionality:

- Core quality
 - **Corrective and preventive action (CAPA)** — The system provides workflow support to respond to a nonconforming or unplanned event through investigation, action plan development, implementation of preventive actions and ensuring no risk of recurrence.
 - **Nonconformance management** — This refers to Identifying, documenting and resolving instances where products or processes do not meet requirements.
 - **Deviations management** — This refers to recording and managing departures from approved procedures,
 - **Audit management** — This pertains to planning, executing and tracking audits to ensure quality standards and regulatory compliance are maintained.
- Change, risk and analysis
 - **Change control** — The system provides workflows and enforcement of processes for managing changes in quality products, processes and services.
 - **Risk assessment** — This refers to the process of identifying magnitude, frequency or likelihood of organizationwide quality risks.
 - **Failure modes and effects analysis (FMEA) or other industry relevant analysis such as HACCP** — The system provides a structured approach to discovering potential failures that may exist within the design of a product or process.
- Document and training
 - **Document management and control** — The system is used for electronic storage, maintenance, version control and retrieval of quality documents, which may include, for example, SOPs, work instructions or engineering change orders.
 - **Employee training and qualification** — The system provides modules for managing responsibilities, training and certification requirements for employees, suppliers and

other partners to monitor and ensure compliance with regard to required training and certification.

- Customer and supplier
 - **Complaint management** — The system provides a workflow to log, manage and track the status of customer complaints.
 - **Supplier quality management (SQM)** — The system provides tools for measuring and managing the quality of direct material suppliers and external manufacturing service providers.

Common Features

- Statistical process control (SPC)
- Industry-specific regulatory compliance features
- Capability for managing electronic batch records
- Predictive analytics for forecasting quality issues and identifying trends
- Automatic identification of deviations or irregularities in product or process quality
- AI functionalities including, but not limited to, document management, training creation and chatbots

Magic Quadrant

Figure 1: Magic Quadrant for Quality Management System Software





Gartner

Vendor Strengths and Cautions

AssurX

AssurX is a Challenger in this Magic Quadrant. Its QMS product is AssurX Enterprise Quality Management Software, which is a highly configurable and scalable platform designed to support quality management across a wide range of regulated industries. Its operations are geographically diversified, and its clients tend to be medium and large-sized organizations in sectors such as life sciences and energy and utilities.

AssurX is expanding its Corrective and Preventive Action (CAPA), Supplier Quality Management, and Risk Management modules. It is developing new solutions for receiving

and inspection management, as well as advanced analytics, with a focus on usability, supply chain quality and development.

Strengths

- **Sales execution/pricing:** AssurX offers competitive pricing and flexible contract terms, including cloud and on-premises subscriptions and perpetual on-premises licenses. It is a cost-effective choice for organizations seeking value and adaptability in their QMS solution.
- **Operations:** AssurX has established a reliable revenue structure, with a significant proportion of revenue derived from direct licensing and maintenance of its proprietary QMS software, supported by well-managed upgrade cycles that minimize downtime. Its privately operated cloud infrastructure enables secure, seamless transitions between cloud and on-premises deployments without functionality gaps or migration fees.
- **Vertical/industry strategy:** AssurX offers a robust feature set tailored to the energy and utilities industry, including advanced capabilities like integrated incident, event and equipment management. In addition to its substantial brand equity and regulatory expertise in the energy and utilities industry, AssurX also serves other industry segments where its depth is not as strong.

Cautions

- **Innovation:** AssurX's AI, automation and integration capabilities are less advanced than those of other vendors in this evaluation. It primarily focuses on AI-driven decision support rather than more sophisticated agentic AI functionalities based on customer feedback.
- **Marketing execution:** AssurX's brand awareness and visibility in this market are limited compared to leading competitors, and it lags behind in terms of innovative marketing methods, user community engagement and brand channel utilization.
- **Offering (product) strategy:** AssurX does not publicly disclose its product roadmap, but shares it with customers and prospects. AssurX has introduced fewer enhancements over the past 12 months compared to other vendors in this evaluation.

ComplianceQuest is a Leader in this Magic Quadrant. Its QMS product is ComplianceQuest Enterprise Quality Management System, which is a cloud-based platform built on Salesforce that provides a fully connected suite of quality management solutions. Its operations are primarily in North America, and its clients tend to be medium and large-sized organizations across life sciences, manufacturing and other regulated industries.

ComplianceQuest is partnering with Salesforce to invest in agentic AI, automating investigations and training, integrating risk management with standardized risk matrices, and providing a zero-training user experience for task completion using familiar tools like Microsoft Teams and email.

Strengths

- **Innovation:** ComplianceQuest's capabilities for AI and automation position it ahead of most competitors. It offers a built-in chatbot and predictive analytics for internal performance and risk analysis, and for supplier performance. Its roadmap includes innovations like AI-driven impact assessments, root-cause analysis and regulatory change detection.
- **Product or service:** ComplianceQuest natively supports all foundational QMS capabilities and delivers an intuitive, role-based user experience across complex, regulated industries. Its modern, user-friendly interface and extensive configurability differentiate its product.
- **Customer experience:** ComplianceQuest customers have consistently reported that the deployment and integration process is smooth and efficient, and they have shared positive feedback about both the implementation and the product as a whole.

Cautions

- **Marketing execution:** ComplianceQuest has lower market visibility and brand awareness than other Leaders in the market, mainly due to its relative newness. Prospective customers should focus on evaluating the solution's capabilities and suitability for their unique requirements, rather than relying solely on brand recognition.
- **Offering (product) strategy:** The speed at which ComplianceQuest releases customer updates, patches and new features can be slower than that of competitors and, therefore, may slow down the availability of new functionality.

- **Geographic strategy:** The majority of ComplianceQuest's customers and operations remain concentrated in North America. The company has articulated plans to broaden its presence in other regions, including Europe and the Asia/Pacific region, as part of its ongoing growth strategy.

Fabasoft

Fabasoft is a Challenger in this Magic Quadrant. Its QMS product is Fabasoft Approve, which is a cloud-based, AI-supported QMS designed to digitize and automate quality processes, document management, and workflow collaboration for regulated industries. Its operations are mainly in Europe, and its clients tend to be large organizations in sectors such as automotive, energy, aerospace and defense, metals, oil and gas, and pharmaceuticals.

Fabasoft is expanding its QMS capabilities through a 12-month roadmap focused on enhanced business process model and notation workflow intelligence, AI, and industry-specific modules, with a focus on strengthening the security, explainability and compliance of its platform.

Strengths

- **Innovation:** Fabasoft's platform includes AI-powered document classification, intelligent search and retrieval, automated workflow management, and robust analytics dashboards. It also presents a strong emerging technology roadmap, with ongoing enhancements in AI, analytics and automation.
- **Product or service:** Fabasoft provides a reliable product with strong emerging technology integrations. With consistently high uptime, robust core capabilities and a user-friendly design, Fabasoft effectively supports efficient quality management and drives strong user adoption.
- **Customer experience:** Fabasoft is easy for customers to deploy. Fabasoft also has robust processes for gathering and acting on customer feedback, which enables the company to deliver product updates that align with customer needs.

Cautions

- **Offering (product) strategy:** Fabasoft's integration capabilities with other enterprise, manufacturing or quality systems are more limited compared to leading vendors, which may present challenges for organizations operating in complex multisystem environments.

- **Sales strategy:** Fabasoft's sales force is effective in engaging quality professionals, but its focus on document and quality management may overlook the broader value chain, where quality technology can deliver significant benefits across multiple functions. Additionally, the lack of dedicated, independent sales teams for each market segment may restrict Fabasoft's ability to tailor solutions and effectively serve the diverse needs of different customer groups.
- **Marketing execution:** Fabasoft's marketing efforts are modest and focus on social media, fairs and practical events such as workshops and webinars. While these events offer value to new and existing customers, they have not been effective in increasing market visibility outside of Europe.

Hexagon (ETQ)

Hexagon (ETQ) is a Leader in this Magic Quadrant. ETQ is a subsidiary of Hexagon. Its QMS product is ETQ Reliance, which is a cloud-based QMS that offers extensive configurability and supports organizations in implementing flexible, data-driven quality processes. Its operations are focused in North America, and its clients tend to be a mix of small, medium and large organizations across sectors such as life sciences, industrial equipment, chemicals, electronics, and food and beverage.

ETQ's roadmap focuses on expanding industry-specific applications and compliance packages, integrating connected worker capabilities, advancing its AI models and predictive analytics, providing platform scalability, and offering an enhanced customer experience.

Strengths

- **Marketing execution:** ETQ demonstrates strong customer engagement and industry presence by hosting proprietary events, participating in large-scale industry gatherings, publishing impactful case studies and fostering active discussion in online forums.
- **Offering (product) strategy:** ETQ exhibits a robust deployment and integration strategy, featuring prebuilt APIs for standard system integrations and third-party applications. It has an extensive network of deployment partners that have completed more than 10 implementations in the last 12 months.
- **Product or service:** ETQ Reliance combines robust out-of-the-box functionality with extensive configurability, providing the flexibility and depth required to serve a diverse

range of industries. Its QMS solution delivers strong overall performance and a user-friendly design.

Cautions

- **Customer experience:** Customers should be aware that ETQ's quality of customer service has reportedly declined following the Hexagon acquisition, with the departure of key personnel and challenges integrating ETQ Reliance into the broader Hexagon organization further impacting the customer experience. However, ETQ has just announced a proposed spin-off from Hexagon to become part of Octave in 2026.
- **Geographic strategy:** ETQ's customer base and operational focus remain heavily concentrated in North America, with EMEA as its second largest region. While ETQ offers global service and support coverage, its ability to provide localized support may be limited. Prospective customers with significant operations outside North America and EMEA should carefully assess ETQ's ability to meet their support needs.
- **Innovation:** ETQ's present AI capabilities are limited to basic generative functions such as document creation, workflow optimization and data entry automation, which are behind more advanced solutions offered by competitors. Although ETQ has announced plans for significant enhancements, including partnerships for predictive quality analytics and connected worker solutions, customers seeking sophisticated AI features should proceed with caution by both validating the planned advancements and timeline to meet their needs.

Honeywell

Honeywell is a Leader in this Magic Quadrant. Its QMS product is TrackWise Digital, which is a cloud-based platform built on Salesforce that provides a QMS designed to digitize and automate core quality processes, document management and compliance. Its operations are geographically diversified, and its clients tend to be large organizations primarily in the life sciences industry.

Honeywell focuses on proactive quality improvement, with a roadmap that includes usability and performance enhancements, new AI-powered modules for quality risk management and root cause analysis, and expanded support for evolving regulatory requirements such as EUDAMED and U.S. FDA API Submission.

Strengths

- **Innovation:** Honeywell has delivered advanced AI capabilities within its QMS platform, including tools for intelligent CAPA recommendations, predictive workload management and semantic data analysis. Honeywell also has an extensive portfolio of patents and a robust roadmap for launching new features in the coming year.
- **Product or service:** TrackWise Digital distinguishes itself with advanced quality management features and strong integration capabilities. Built natively on Salesforce, it enables seamless data sharing and regular update cadence, ensuring access to the latest innovations with minimal disruption.
- **Geographic strategy:** Honeywell has built a strong global footprint in both established and emerging markets. It has a track record of proactively establishing its presence in emerging markets before they mature to secure an incumbent status. Honeywell has recently enhanced its localized support across the U.S., Europe and Asia, ensuring regional compliance and investing in infrastructure.

Cautions

- **Sales execution/pricing:** Honeywell's proof-of-concept requirements are resource-intensive but typically reserved for complex or unique implementations, representing a small portion of new deployments. Honeywell's primary reliance on annual user-based licensing may limit flexibility for some customers and, compared to other vendors evaluated, discounts are limited outside of multiyear contract agreements.
- **Vertical/industry strategy:** Except for the life sciences industry, Honeywell lacks out-of-the-box, industry-specific feature sets. Additionally, it dedicates few resources to verticals outside of life sciences, which may impact the solution's effectiveness in other industries.
- **Customer experience:** Honeywell's customers should be aware that involvement during processes such as data migration and technical support can be high, which may require significant time and resources. While Honeywell does offer dedicated partners to assist with these efforts, customer feedback has highlighted concerns around usability and the fulfillment of roadmap commitments. It is important to note that much of this feedback may relate to the legacy TrackWise on-premises solution rather than the newer TrackWise Digital platform.

Ideagen is a Challenger in this Magic Quadrant. Its QMS product is Ideagen Quality Management, which is a cloud-based platform that centralizes quality data and automates workflows for document review, incident investigation, compliance monitoring and supplier management. Its operations are geographically diversified, and its clients tend to be medium to large organizations in regulated industry sectors such as manufacturing, aerospace, food and beverage, and life sciences.

Ideagen is investing in expanding AI-driven automation, enhancing real-time visibility and predictive analytics, and accelerating out-of-the-box functionality to reduce implementation time and support in evolving global compliance requirements.

Strengths

- **Sales execution/pricing:** Ideagen positions its QMS solutions at a more competitive price point compared to other vendors in this evaluation. This is complemented by flexible contract structures, allowing customers to tailor agreements to their specific needs and budget requirements, making it accessible to a broader range of organizations.
- **Vertical/industry strategy:** Ideagen has significantly expanded its industry-specific capabilities through a series of mergers and acquisitions, including DevonWay, Qadex and Safefood 360. The merger with DevonWay expands Ideagen's industry-specific capabilities, notably in energy and mining, strengthening its competitive position.
- **Product or service:** Ideagen Quality Management provides a comprehensive feature set that aligns well with customer requirements and industry standards. It is powerful in terms of document control, audit management and regulatory compliance, offering robust tools for managing quality processes in highly regulated environments.

Cautions

- **Innovation:** Ideagen's AI capabilities currently center on generative functions such as document creation, text extraction and basic automation. These features are fairly basic compared to those of its competitors. To address this, the vendor has recently launched its own agentic AI platform.
- **Sales strategy:** Ideagen trails some vendors in this research in terms of direct sales resources or local expertise in North America, Latin America and parts of the Asia/Pacific region. It often relies on a network of resellers, partners and channel sales rather than a large, direct enterprise sales force. This is something the vendor is working on enhancing with its recent opening of an office in the U.S.

- **Offering/product strategy:** Due to multiple mergers and acquisitions, Ideagen customers should work with the vendor to validate which products will be prioritized, updated or phased out. This validation will help make decisions that are best aligned with consistent functionality, enabling long-term planning and informed decision making. Despite these organizational changes, legacy DevonWay and Ideagen solutions have integrated more smoothly than expected.

MasterControl

MasterControl is a Leader in this Magic Quadrant. Its QMS product is MasterControl Quality Excellence, which is a cloud-based, end-to-end digital QMS designed to automate and streamline compliance, document control, training and quality event management. Its operations are geographically diversified, and its clients tend to be small, medium and large organizations in life sciences.

MasterControl's roadmap focuses on expanding AI-powered compliance automation, real-time regulatory intelligence, predictive audit readiness and advanced business process mapping. It also plans to reduce complexity and enhance user experience through proactive, push-based automation.

Strengths

- **Market understanding:** MasterControl demonstrates a clear QMS vision, particularly in U.S. FDA-regulated spaces, with decisions that account for risks and emerging trends to address compliance needs and other customer requirements effectively.
- **Product or service:** MasterControl Quality Excellence offers an extensive suite of capabilities, including automated and traceable change control, robust CAPA and complaint management, integrated document control, and advanced audit and risk assessment tools. These are all tightly aligned with global regulatory standards and FedRAMP-authorized cloud architecture.
- **Geographic strategy:** MasterControl has focused on accelerating growth in the EMEA and Asia/Pacific regions. The company has established offices in key cities, including London, Tokyo, Singapore, Melbourne and, most recently, Hyderabad, India.

Cautions

- **Vertical/industry strategy:** Except for the life sciences industry, MasterControl's product lacks out-of-the-box, industry-specific feature sets across all vertical markets it serves.

Additionally, it dedicates few resources to verticals outside of life sciences, which may impact the solution's effectiveness in other industries.

- **Customer experience:** Customers report challenges with MasterControl's customer support responsiveness and the quality of technical support. Usability has also been cited as a concern, with some customers describing the interface as outdated or unintuitive. While there are positive reports regarding recent improvements and user friendliness, prospective customers should carefully evaluate whether the current interface and support model meet their expectations.
- **Operations:** MasterControl's deployment process can be resource-intensive and complex, often requiring significant customer involvement and a reliance on MasterControl's own services for successful implementation and validation. Although some customers have reported faster implementation and strong validation tools compared to competitors, organizations should be prepared for a potentially high level of engagement during deployment.

Omnex Systems

Omnex Systems is a Visionary in this Magic Quadrant. Its QMS product is EQMS.AI, which is a unified, AI-enabled platform that can be tailored to align with industry standards and operational needs. EQMS.AI helps organizations to digitalize new product development processes and accelerate defect prevention. Its operations are geographically diversified, and its clients tend to be medium to large organizations in the automotive and semiconductor sector.

Omnex's roadmap focuses on expanding AI enablement across all modules, supporting integrated engineering and compliance, enhancing quality, health, safety and environmental functionality, strengthening supplier management with AI and providing hypercustomization for new product development.

Strengths

- **Innovation:** Omnex has delivered advanced AI capabilities across its QMS platform, including AI-driven FMEA generation and validation, intelligent CAPA recommendations, and automated audit planning. Omnex maintains a robust roadmap focused on AI enablement and hypercustomization.
- **Market understanding:** Omnex demonstrates a clear QMS vision, particularly in highly complex sectors such as automotive and semiconductor, with decisions that account for

risks and emerging trends to address compliance needs and other customer requirements.

- **Customer experience:** Customers report an overall positive customer experience. Omnex leverages customer input to drive product enhancements and align updates with real-world needs. Omnex emphasizes a consultancy approach to deployment, with preconfigured best-practice workflows and a structured implementation process.

Cautions

- **Operations:** Omnex primarily relies on direct delivery, which may constrain its ability to scale global and regional operations compared to other vendors in this Magic Quadrant. Additionally, Omnex's peer community is smaller and less active, limiting opportunities for customer collaboration and knowledge sharing relative to competitors in the market.
- **Vertical/industry strategy:** Omnex is recognized for its expertise in supporting highly complex industries, which is reflected in its strong emphasis on APQP (new product development), FMEA and extensive customization capabilities. While these strengths are valuable for sectors with rigorous quality and process requirements, the level of hypercustomization and FMEA focus may exceed the needs of some industries, potentially making the solution less optimal for organizations seeking more standardized approaches.
- **Sales execution/pricing:** Omnex provides a subscription-only pricing model, which offers less flexibility compared to some of the evaluated vendors with a broader range of licensing options. Omnex's sales organization is fully direct and not segmented by industry vertical, which may limit its ability to deliver highly tailored sales engagement.

QAD

QAD is a Niche Player in this Magic Quadrant. Its QMS product is QAD EQMS, a cloud-based solution designed to centralize control of documents, training, risks, audits and supplier management. This enables manufacturers to ensure compliance, prevent costly quality failures and optimize processes across their supply chain. Its operations are geographically diversified, and its clients tend to be medium-sized organizations in the automotive and life sciences sectors.

QAD's roadmap focuses on enhancing supplier quality and collaboration, and deepening integration with QAD Adaptive ERP and other enterprise systems. QAD continues to invest in

mobile access and regulatory compliance capabilities to help customers manage quality across global supply chains.

Strengths

- **Sales execution/pricing:** QAD distinguishes itself by offering AI capabilities including document summarization, process automation and automated data analysis as standard features available to all users at no additional cost. In contrast to many competitors that charge extra for similar functionalities, QAD also maintains a lower average price point, providing strong value for customers.
- **Vertical/industry strategy:** QAD offers a robust feature set tailored to the automotive industry, including advanced capabilities like APQP and PPAP workflows. In addition to holding brand equity in the automotive sector, QAD also serves other industry segments where its depth is not as strong.
- **Marketing execution:** QAD maintains strong brand recognition among quality professionals and high visibility within the industry. QAD's consistent engagement on digital platforms, sponsorship of key conferences and publication of educational resources further reinforce its reputation and ensure ongoing prominence among quality professionals.

Cautions

- **Offering/product strategy:** QAD has not delivered a clear strategic roadmap for its product. Its current offering has minimal integration capabilities outside of QAD compared to competitors. However, the strategic alliance with Boomi is expected to enhance QAD's integration capabilities moving forward.
- **Sales strategy:** QAD lacks a clear customer retention strategy and its sales team structure is less robust than that of its competitors, with limited engagement from quality leaders in typical buyer roles.
- **Innovation:** QAD's capabilities for AI, automation and analytics, as well as its proprietary technologies, are less sophisticated than those of other vendors in this evaluation, and plans for future enhancements remain unclear. Usability has been a persistent issue, with some customers reporting minimal progress since QAD acquired the heritage CEBOS solution.

Rockwell Automation (Plex) is a Niche Player in this Magic Quadrant. Plex is a subsidiary of Rockwell Automation. Its QMS product is Plex Quality Management System, which is a cloud-based solution designed for manufacturers that provides real-time data capture, error-proofing and compliance management. Its operations are geographically diversified, and its clients tend to be small and medium-sized organizations in automotive, food and beverage, metals, industrial equipment, and aerospace.

Plex's roadmap includes API development for checksheet integration, the FactoryTalk Analytics VisionAI interface for enhanced vision system connectivity, FSMA Section 204(d) feature refinement, and updates to its HACCP and FMEA modules.

Strengths

- **Operations:** Plex has established a solid revenue structure and efficient release cycles while ensuring minimal downtime and sustaining an active product community. A significant proportion of revenue is derived from the direct licensing and maintenance of its proprietary QMS software.
- **Market understanding:** Plex leverages its deep heritage in automotive disciplines, such as FMEA, PPAP, and APQP, and extends these capabilities to meet the requirements of adjacent manufacturing industries in verticals such as food and beverage and consumer packaged goods.
- **Geographic strategy:** Plex maintains a strong presence in North America, Europe and the Asia/Pacific region, with a particular emphasis on expanding throughout the Asia/Pacific region. Targeted investments in local expertise and infrastructure enable Plex to meet customer needs effectively in this high-growth area.

Cautions

- **Offering (product) strategy:** Plex's product strategy is focused on deep integration within manufacturing execution, which limits the platform's extensibility and connectivity with adjacent solutions such as CRM systems, compared to other vendors in this evaluation. Organizations seeking a more unified or flexible technology ecosystem across their enterprise should proceed with caution by validating integration capability for their unique use case.
- **Vertical/industry strategy:** Plex is not built for or sold to some highly regulated industries. The QMS does not offer regulatory-specific validation or compliance capabilities.

Prospects in life sciences (pharmaceutical and biotech) or energy industries should consider other vendors.

- **Marketing execution:** Customer awareness of Plex's stand-alone QMS software remains relatively low, as the brand is primarily associated with MES systems and there are few public case studies highlighting its QMS capabilities.

Siemens

Siemens is a Leader in this Magic Quadrant. Its QMS products are Teamcenter Quality and Opcenter X Quality, which are each cloud-based and on-premises solutions designed to integrate quality planning, execution and improvement across the product life cycle. Its operations are geographically diversified, and its clients tend to be large organizations in automotive, aerospace, life sciences, industrial equipment and electronics.

Siemens' roadmap includes digital thread integration, AI-driven automation and cloud-native scalability. Key investments include enhanced model-based FMEA, predictive analytics, advanced supplier and customer collaboration modules, AI-powered audit and document management, and SaaS-based modular offerings for highly regulated industries.

Strengths

- **Innovation:** Siemens delivers a highly advanced, integrated approach to quality management by embedding generative AI, predictive analytics, AR/VR, digital twin technology, IoT and RPA across the entire quality life cycle. Solutions like Industrial Copilots and Insights Hub proactively identify defects, optimize processes and enable continuous improvement through real-time and historical data analysis, immersive training, and automated workflows.
- **Vertical/industry strategy:** Siemens delivers a robust feature set tailored to complex manufacturing environments, including advanced capabilities centered around the digital twin vision. In addition to Siemens' substantial brand equity across complex manufacturing industries, it also serves other industry segments where its regulatory depth is not as strong.
- **Sales strategy:** Siemens leverages dedicated sales and technical teams, has implemented a proactive retention strategy, and fosters customer communities and co-innovation through focused customer success initiatives.

Cautions

- **Product or service:** Siemens' QMS product features and interface are structured like engineering systems, making them less intuitive for users outside of that domain. Siemens' QMS products are not frequently purchased as stand-alone offerings by large enterprise customers as they typically seek the benefits of a digital thread solution that involves PLM and/or MES.
- **Operations:** Siemens' strategic message on dedicated QMS investment is unclear to some customers. While Siemens does offer a stand-alone QMS system, the company is heavily invested in digital twin and end-to-end digital thread initiatives, with QMS positioned as one component within this broader vision.
- **Sales execution/pricing:** Siemens tends to have higher pricing and greater proof-of-concept resource requirements compared to other vendors evaluated, which may present barriers for some customers.

Veeva Systems

Veeva Systems is a Leader in this Magic Quadrant. Its QMS product is Veeva QMS, a cloud-based QMS designed for the life sciences industry offering workflows for managing deviations, complaints, audits, risk, supplier quality and change control. Its operations are geographically diversified, and its clients tend to be large life sciences organizations.

Veeva's roadmap is focused on innovation, with three major releases per year. Its upcoming releases emphasize life sciences-specific best practices, the release of AI-powered features and expanding integrations across the Veeva Quality Cloud to drive efficiency, collaboration and regulatory compliance for customers worldwide.

Strengths

- **Vertical/industry strategy:** Veeva QMS provides industry-leading usability and feature depth for the life sciences industry, featuring advanced capabilities such as electronic batch release and supplier portals. In addition to its substantial brand equity in life sciences, Veeva also serves other industry segments where its depth is not as strong.
- **Customer experience:** Veeva customers report exceptional customer experience through ease of integration and deployment, a comprehensive support approach, and dedicated data migration roles. It uses multiple channels for gathering and responding to customer feedback, including direct engagement with product development teams.

- **Geographic strategy:** Veeva maintains dedicated teams in North America, Europe, the Asia/Pacific region and Latin America, enabling responsive, end-to-end support at local, regional, and global levels. This structure ensures product alignment with customer needs and cultures worldwide.

Cautions

- **Innovation:** Veeva currently offers no out-of-the-box AI capabilities. However, it has announced plans to expand AI agents and enable custom agent development in the next 12 months.
- **Sales execution/pricing:** Veeva's pricing is significantly higher than that of competitors, with limited discounting and a less mature proof-of-concept process. The price point of its solution is out of reach for many customers.
- **Sales strategy:** Veeva's retention strategy highlights its dedication to the life sciences industry; however, it has historically been focused on life sciences and closely adjacent markets, lacking broader market focus.

Inclusion and Exclusion Criteria

To qualify for inclusion in this Magic Quadrant, providers need to have the following.

eQMS market presence:

- A credible, stand-alone eQMS product with at least 250 live customers.
- At least \$20 million in eQMS annual revenue from direct licensing and maintenance of its proprietary eQMS product, excluding revenue from other vendor product offerings, third-party products, services or unrelated offerings.
- The eQMS product must be sold and marketed as a stand-alone, self-serve application and used independently of other services offered by the vendor.

Global eQMS presence:

- Must have eQMS customer* references in at least two of the following geographic regions: North America, Central America, South America, Europe, the Middle East, Africa and the Asia/Pacific region.

- Must have a minimum of 10 customers outside of its home geographical region.

Cross-industry presence:

The provider must have new and existing eQMS customers* in at least three industries.

Examples include:

- Aerospace and defense (final assembly and suppliers)
- Automotive OEMs and suppliers
- Chemicals (bulk and specialty)
- Consumer packaged goods
- Electronics (peripherals, mobile phones)
- Food and beverage
- General discrete (includes engines, machinery, construction, factory equipment)
- Life sciences (medical devices)
- Life sciences (pharmaceutical and biotech)
- Metals (primary and fabricated)
- Mill products (paper and pulp)
- Oil and gas (exploration, development, refining)
- Semiconductor
- Textiles/apparel

Full eQMS functionality:

The provider's eQMS software must have the following functionality:

- Change control
- Corrective and preventive action
- Complaint management

- Nonconformance management
- Deviations management
- Document control and management
- Failure modes and effects analysis or other industry-relevant analysis
- Audit management
- Risk assessment
- Supplier quality management
- Tracking of training and qualification

QMS innovation:

- Must demonstrate active investment and development in at least one transformational technology, as identified in the **Hype Cycle for Quality Management, 2025**, with clear evidence of these capabilities being incorporated into the QMS platform and at least 20 customer references:
 - IoT connectivity, analytics, digital twin or AI.
- The QMS solution must provide native or API-based integration with a minimum of three enterprise systems from the following list: ERP, MES, PLM, CRM, LIMS, SCM, HRMS or DMS. Integrations must support real-time data exchange and workflow automation.

Gartner excluded providers that offer stand-alone manufacturing or risk software applications, such as MES, PLM, EHS or risk-only software solutions, from this Magic Quadrant. Gartner also excluded any provider that does not sell eQMS as a stand-alone solution. In cases where a vendor sells eQMS in addition to other technology offerings or services, it will only be considered if it sells eQMS as a stand-alone solution and meets all the inclusion criteria for that solution alone.

* The definition of a customer is a single legal entity independently and holistically using the eQMS stand-alone solution being evaluated. This does not include customers using other products sold by the vendor and complementary add-ons.

Honorable Mentions

In addition to the vendors profiled in this Magic Quadrant, we have identified additional providers that did not meet all the inclusion criteria for this evaluation. These Honorable Mentions fall into three categories: providers with limited market presence, providers that offer QMS systems as part of a broader ecosystem and providers that offer market-specific QMS systems.

Limited Market Presence

AlisQI: AlisQI delivers intelligent AI assistants powered by GenAI for support, onboarding and continuous improvement, offering context-aware recommendations for configuration and business logic. Its robust APIs enable real-time industrial Internet of Things (IIoT) data integration, dynamic dashboards and automated escalation workflows. The advanced workflow engine supports RPA, orchestrating seamless data transfer and process automation, thus positioning AlisQI as an active process guide rather than just a system of record. AlisQI was not included in this evaluation as it did not meet the eQMS market presence inclusion criteria.

Propel: Propel integrates agentic AI into its Salesforce-native QMS solution, automating document summaries, training quiz generation and leveraging change management to streamline compliance, decision making and workflows. Open APIs support robust integrations, while unified product data management enables the creation of digital twins to facilitate closed-loop quality. Propel connects physical and digital data for more innovative life cycle management. Propel was not included in this evaluation as it did not meet the eQMS market presence inclusion criteria.

QMS Systems That Are Part of a Broader Ecosystem

Cority: Cority's quality management solution automates audits, inspections and workflows, enhancing traceability and supplier performance. Its centralized oversight and closed-loop issue management help organizations ensure audit readiness and global compliance. Cority was not included in this evaluation as its quality management solution is delivered within a broader environment, health, safety and quality (EHSQ) platform rather than as an independent eQMS.

Dassault Systèmes: Dassault Systèmes' Quality Management module on the 3DEXPERIENCE platform offers quality assurance for discrete and regulated industries. This features proactive risk mitigation in the early stages of the product shortlist and establishes a

feedback loop with data from manufacturing and services. Dassault Systèmes was not included in this evaluation as the overall quality management solution is part of the 3DEXPERIENCE platform rather than a stand-alone eQMS.

Intelex: Intelex Quality Management Software streamlines quality processes with nonconformance reporting, advanced tools (FMEA, APQP, PPAP), integrated document management and robust workflows. Its SaaS platform supports comprehensive quality life cycle management and drives continuous improvement across organizations. Intelex was not included in this evaluation as its solution is part of a broader EHSQ platform rather than a stand-alone eQMS.

Oracle: Oracle Fusion Cloud Quality Management offers closed-loop quality control with AI, ML and IoT, including configurable standards, supplier management, predictive analytics and mobile collaboration. Its comprehensive supply chain visibility and analytics help organizations proactively address quality issues and improve performance. Oracle was not included in this evaluation as its quality management is delivered within a broader ERP and supply chain suite rather than as an independent eQMS product.

PTC: Arena and Windchill QMS are cloud-native solutions integrated with PTC's PLM platforms, enabling organizations in automotive, aerospace and defense, electronics, life sciences, and semiconductors to connect quality and product design processes. PTC drives compliance and collaboration through AI-powered assistance, OpenAPI integration and advanced analytics. PTC was not included in this evaluation as its quality management functionality is delivered as part of a comprehensive PLM platform rather than as an independent eQMS product.

SAP: SAP Quality Management (QM) is embedded in SAP S/4HANA (SAP Cloud ERP), supporting ISO 9000 compliance and integrating quality tasks across manufacturing and supply chain. Its deep integration enables organizations to embed quality management into their core business processes, resulting in greater efficiency and control. SAP was not included in this evaluation, as its quality management functionality is part of a broader ERP suite rather than a stand-alone eQMS solution.

Market-Specific QMS Systems

Greenlight Guru: Greenlight Guru offers an eQMS and clinical data suite for medical device companies, streamlining compliance and patient outcomes with integrated risk and audit-ready workflows. The platform's robust controls and life cycle management tools are

specifically designed to meet the stringent regulatory requirements of the medical device sector. Greenlight Guru was not included in this evaluation as its exclusive focus on medical devices limits its cross-industry applicability, which is required for inclusion.

TraceGains: TraceGains automates quality and compliance for the food and beverage industry, offering configurable FSMA/GFSI templates, workflows and centralized documentation. Its platform streamlines supplier management and provides real-time insights for plant floor operations. TraceGains was not included in this evaluation as its specialization limits its cross-industry applicability, which is required for inclusion.

Evaluation Criteria

Ability to Execute

In this Magic Quadrant, Gartner evaluated vendors based on several Ability to Execute criteria. Below are the criteria assessed relevant to this market.

Criteria Evaluated

Product or Service: Key capabilities, delivery and execution, and product performance

Sales Execution/Pricing: Pricing model, licensing flexibility and contracting terms

Marketing Execution: Utilization of brand channels, market visibility and brand name recognition

Customer Experience: Customer satisfaction, overall deployment and customer support

Operations: Overall operations health, resource management, and ethics, data standards and transparency

Criteria Not Evaluated

Overall Viability: This criterion, which typically assesses a vendor's financial health and long-term sustainability, was not considered directly relevant to the QMS market for this evaluation as all vendors included are already well-established and financially stable.

Market Responsiveness/Record: This criterion was excluded because the focus of this Magic Quadrant is on current product capabilities and customer experience rather than historical responsiveness or track record in the market.

Table 1: Ability to Execute Evaluation Criteria

<i>Evaluation Criteria</i>	<i>Weighting</i>
Product or Service	High
Overall Viability	Not Rated
Sales Execution/Pricing	Medium
Market Responsiveness/Record	Not Rated
Marketing Execution	Low
Customer Experience	High
Operations	Medium

Source: Gartner (January 2026)

Completeness of Vision

In this Magic Quadrant, Gartner evaluated vendors based on several Completeness of Vision criteria. Below are the criteria assessed relevant to this market.

Criteria Evaluated

Market Understanding: Market awareness, company vision and strategic focus, and regulatory and competitive differentiators

Sales Strategy: Customer and channel strategy, resourcing and positioning, and buyer personas

Offering (Product) Strategy: Product roadmap, integrations, and mergers and acquisitions

Vertical/Industry Strategy: Market segment understanding, clear and consistent vertical focus, and vertical investments

Innovation: Emerging technology adoption, use of transformational technology, and innovation indicators

Geographic Strategy: Market segment understanding, clear and consistent geographical focus, and geographic investments

Criteria Not Evaluated

Marketing Strategy: This criterion was incorporated into the evaluation of sales strategy, as the effectiveness of marketing is closely tied to how vendors position and sell their QMS solutions. As a result, it was not evaluated as a stand-alone criterion.

Business Model: This criterion was excluded because variations in business models do not significantly impact the core capabilities or value proposition of QMS solutions for most customers in this market.

Table 2: Completeness of Vision Evaluation Criteria

<i>Evaluation Criteria</i>	<i>Weighting</i>
Market Understanding	High
Marketing Strategy	Not Rated
Sales Strategy	Low
Offering (Product) Strategy	High
Business Model	Not Rated
Vertical/Industry Strategy	Medium
Innovation	High

<i>Evaluation Criteria</i>	<i>Weighting</i>
Source: Gartner (January 2026)	

Source: Gartner (January 2026)

Quadrant Descriptions

Leaders

Leaders provide mature, comprehensive quality management solutions that meet the current demands of various industries, including regulated ones, and have demonstrated the vision and innovation necessary to sustain their market position as quality and compliance requirements evolve. Leaders are the vendors to watch for insight into how new QMS offerings and best practices are likely to develop.

Leaders typically have a large, satisfied customer base (relative to the size of the QMS market) and enjoy high credibility among quality professionals. Their scale and financial strength enable them to remain viable and continue investing in product development, even in challenging economic conditions. Leaders generally address a wide range of QMS requirements, supporting broad industry needs for compliance, risk management and process improvement.

Challengers

Challengers have a strong Ability to Execute but may not have a plan that will maintain a strong value proposition for new customers, especially as emerging technologies begin to play a larger role in the quality management market. Although Challengers typically have significant size and financial resources, they may lack strong vision, innovation or an overall understanding of market needs. While Challengers may offer mature QMS solutions that are well-established in traditional industries, these products can be approaching the end of their innovation cycle. They may primarily serve a large, but gradually shrinking, segment of the market.

As customer expectations evolve and regulatory requirements become more complex, Challengers risk falling behind without a commitment to innovation and a deeper understanding of shifting market needs. Challengers have the potential to become Leaders if they invest in modernizing their QMS offerings and develop a more compelling vision for the

future. It is not uncommon for large vendors to move between the Challengers and Leaders quadrants as their product strategies and the needs of the QMS market change over time.

Visionaries

Visionaries are vendors whose strategies align with Gartner's perspective on the future evolution of the industry; however, their ability to consistently deliver on that vision remains less established. The limited number of Visionaries in the current QMS Magic Quadrant highlights an active acquisition strategy among some vendors, where larger players frequently acquire innovative companies before they can fully mature or disrupt the market.

Visionaries typically represent a higher-risk, higher-reward option for both vendors and customers: they are often first to introduce new technologies, services or business models, but may still be building out their financial resources, support infrastructure and distribution channels. The future trajectory of Visionaries — whether they become Challengers, Leaders or acquisition targets — depends on market acceptance of their innovations and their ability to forge partnerships that complement their strengths.

Niche Players

In the QMS market, Niche Players tend to excel within a specific segment, such as a particular industry vertical, geographic region or specialized functionality. Their limited ability to innovate or compete across the broader QMS landscape may stem from a deliberate focus on these areas or challenges in adapting to evolving market expectations. Some Niche Players may offer a reasonably comprehensive QMS solution, but often have restricted implementation and support resources, and typically serve a smaller customer base. Compared to vendors in other quadrants, Niche Players generally lack a strong, forward-looking vision for their offerings.

For QMS buyers, evaluating Niche Players can be more complex than assessing Leaders or Challengers. Some Niche Players may be well-positioned to grow or expand their capabilities. However, others may struggle to execute and keep pace with the rapid evolution of QMS requirements, such as integration with emerging technologies, global compliance standards or advanced analytics. A Niche Player could be an ideal fit if your organization's needs align closely with its strengths; however, careful consideration of the product roadmap, support capabilities and alignment with your future requirements is essential when selecting a Niche Player.

Context

This Magic Quadrant provides a comparative analysis of leading QMS vendors, offering actionable insights into each provider's strengths and weaknesses. Use this resource as a strategic guide to identify, compare, and shortlist vendors that best match your organization's specific requirements and long-term vision. As the market evolves with increasing emphasis on immediate value, intuitive user experiences, robust compliance, and advanced technologies, thorough vendor evaluation is more critical than ever.

Key considerations and recommended next steps for clients include:

- **Prioritize fit and flexibility.** Start by mapping your organization's workflows, regulatory requirements, technology preferences and integration needs. Utilize Gartner's RFP templates to structure and streamline this process (see [Toolkit: RFP for Quality Management System Software](#)).
- **Scrutinize AI and automation claims.** With heightened interest in AI, automation and advanced analytics, it's essential to schedule live demos, ask for specific examples of features in use, and request metrics or case studies showing measurable improvements. Confirm that these features are genuinely embedded and deliver measurable value, reflecting the realities of today's market. Request documentation and client references showing integration and measurable outcomes (e.g., reduced manual tasks, improved compliance rates). For guidance, refer to [AI Use-Case Assessment for Supply Chain Quality Management](#).
- **Verify integration strength.** Effective quality management relies on seamless connectivity with your existing enterprise systems. Request evidence of robust integration capabilities with ERP, MES, CRM, PLM and other critical platforms to ensure comprehensive data visibility and process alignment.
- **Leverage customer references.** Strengthen your evaluation by seeking references from current customers. Focus on real-world deployment scenarios and outcomes to validate vendors' capabilities and claims. Ask customer references for details on implementation, integration challenges, time to value, ongoing support and quantifiable results.
- **Align QMS selection to strategic priorities.** Ensure that your QMS software selection process is closely aligned with your organization's overarching strategic goals. Meet with

stakeholders to define top strategic priorities and use them as criteria to score vendors during selection. Leverage Gartner's guidance to structure your approach and maximize business impact (see [Take These 4 Steps in QMS Software Selection to Support Strategic Objectives](#)).

- **Review roadmaps and future direction.** Request each vendor's roadmap, compare planned features to your future needs (both short term and long term), and exclude vendors with plans that do not support your requirements. For a more specialized focus, leverage [Tool: Quality Management System Software Vendor Evaluation Template](#).

Market Overview

The QMS software market is at the forefront of digital transformation, enabling organizations to move beyond traditional, paper-based processes to fully integrated digital platforms. Businesses are increasingly adopting advanced solutions to streamline quality management, ensure regulatory compliance, and foster continuous improvement.

Market Size and Growth

The QMS software market is experiencing rapid growth. Gartner projects that the global QMS software shortlist will surpass \$10 billion in 2025, representing a 26% increase over 2024 (up from a 22% year-over-year growth rate between 2023 and 2024). This upward trajectory highlights both rising demand for advanced quality management solutions and the steadily improving capabilities of QMS solutions.

Vendor Trends

These include:

- **Cloud-native dominance.** QMS software vendors are shifting toward cloud-native architectures. SaaS deployments now account for approximately 85% of all implementations, whereas on-premises solutions represent just 7% of the market, hosted deployments comprise 4% and other deployment models make up the remaining 5%.
- **AI, automation and analytics innovation.** Although most out-of-the-box QMS capabilities remain relatively basic, vendors are aggressively investing in AI, automation and advanced analytics to differentiate their platforms. The most impressive features available today include AI-powered decision support for CAPA and audit management, predictive

risk assessment, and robust automation that streamline quality workflows. Looking ahead, vendor roadmaps highlight the rapid expansion of conversational AI, self-service advanced analytics and agentic AI designed to guide users through complex quality processes and deliver deeper, predictive insights for proactive quality management.

- **Expanded integration capabilities.** Vendors are enhancing their QMS platforms to seamlessly connect with a wide array of enterprise systems, including ERP, MES, LIMS, CRM, PLM, EHS, DMS, RIMS, HR and third-party applications, as well as advanced technology platforms.
- **Strategic partnerships and acquisitions.** Strategic technology partnerships and acquisitions are increasingly common as vendors seek to expand their capabilities, enter new verticals and consolidate their market position.
- **Mature revenue structure.** The revenue structure of vendors has stabilized, with an average of 70% of revenue derived from the license and maintenance of proprietary software, 18% from implementation and consulting, 9% from services, and 3% from other sources.

Customer Expectations

These include:

- **Configurable, modular flexibility.** Customers expect QMS platforms to offer extensive configurability and modularity so they can tailor solutions to their unique industry workflows and regulatory demands. Cloud-native, SaaS-based architectures have become the preferred choice for customers, valued for their rapid deployment, scalability, minimal operational disruption and faster time to value.
- **Advanced technology and automation.** Organizations are seeking QMS platforms that extend well beyond basic document management and CAPA workflows. Buyers now expect comprehensive, end-to-end automation that streamlines quality processes, minimizes manual intervention and accelerates issue resolution. Simultaneously, interest in AI and advanced analytics is surging. Since most quality teams lack the in-house expertise to develop these capabilities independently, customers are prioritizing solutions that provide cutting-edge AI and analytics technologies out of the box.
- **Cloud-native dominance.** Customers now expect QMS solutions to be delivered as cloud-native, SaaS offerings, reflecting the market's overwhelming shift toward these architectures. Most organizations view on-premises or hosted deployments as

exceptions, anticipating that vendors will prioritize scalable, secure and easily updated cloud-based platforms.

- **Intuitive user experience.** Usability is a critical differentiator in the QMS market. Customers prioritize platforms with intuitive interfaces and seamless mobile accessibility. Frictionless navigation and robust self-service features are now expected, enabling users at all levels to manage quality processes efficiently and effectively.
- **Comprehensive compliance and audit readiness.** As regulatory environments continue to grow increasingly complex, buyers require QMS platforms that deliver robust, audit-ready compliance capabilities. Support for global standards such as ISO, FDA and GxP is essential, along with tools that simplify regulatory reporting and ensure continuous readiness for audits.
- **Seamless enterprise integration.** Truly holistic quality management relies on the ability to integrate QMS platforms with a wide range of enterprise systems. Seamless connectivity and real-time data visibility across the enterprise are now non-negotiable requirements.

This new Magic Quadrant replaces the Market Guide for Quality Management System Software. The Magic Quadrant offers a more rigorous, comparative analysis, enabling organizations to make more informed decisions as they navigate this dynamic market.

⊕ Evidence

⊕ Evaluation Criteria Definitions

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