

Saudi Arabia Pharmaceutical Quality Management Software Market By Application (Data Management, Training management, Supplier management, Regulatory and Compliance Management, Corrective Action Preventive Action (CAPA) Management, Audit Management, Change Management, Non-Conformances Management, Inspection Management, Risk Management, Others), By Deployment (Cloud-based & Web-Based, On-premises), By Region, Competition, Forecast & Opportunities, 2020-2030F

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Abstracts

Saudi Arabia Pharmaceutical Quality Management Software Market was valued at USD 14.48 Million in 2024 and is anticipated to project robust growth in the forecast period with a CAGR of 10.85% through 2030. The pharmaceutical quality management software (PQMS) market in Saudi Arabia is experiencing robust growth, primarily fueled by the expansion of the country's pharmaceutical industry and the rising adoption of digital technologies aimed at optimizing quality control operations. The incorporation of cutting-edge technologies, such as cloud computing and artificial intelligence, into PQMS solutions is significantly enhancing data management, improving traceability, and streamlining decision-making processes across the sector. This market is poised for continued growth, driven by stringent regulatory requirements, technological innovation, and the accelerated development of the local pharmaceutical landscape. Industry players should prioritize innovation in their offerings and ensure rigorous compliance to effectively capitalize on the burgeoning opportunities in this high-growth market.

Key Market Drivers

Rising Demand for Automation and Efficiency

The rising demand for automation and efficiency is a critical driver in the growth of the Saudi Arabian Pharmaceutical Quality Management Software (PQMS) market. As the pharmaceutical industry faces mounting pressures to meet increasing regulatory standards, improve operational performance, and maintain high-quality products, automation has become essential for streamlining processes and ensuring consistent outcomes. In Saudi Arabia (KSA), digital healthcare has the potential to significantly enhance healthcare efficiency and improve outcomes, with an estimated value of up to \$27 billion by 2030.

Manual processes in pharmaceutical quality management, such as paper-based record keeping, manual inspections, and data entry, are not only time-consuming but also prone to human error. These errors can lead to significant issues, including compliance failures, production delays, and quality lapses that ultimately affect a company's reputation and profitability. The rising demand for automation within the pharmaceutical sector is driven by the need to minimize these human errors and inefficiencies. Automated PQMS solutions streamline routine tasks like data collection, validation, and reporting, which allows quality control teams to focus on more strategic activities. By automating these processes, companies can enhance their operational efficiency, ensure more accurate data, and reduce the risk of non-compliance. This efficiency is especially crucial in a regulatory environment like Saudi Arabia's, where adherence to strict standards is paramount. In an increasingly competitive global pharmaceutical market, time-to-market has become a key factor for companies aiming to maximize profitability. The demand for automation in PQMS is driven by the need for faster, more streamlined processes that reduce the time it takes to develop, manufacture, and distribute pharmaceutical products. Automation allows for continuous monitoring of production stages, real-time issue detection, and immediate corrective actions, which accelerates the quality control process. By automating quality checks and inspections, pharmaceutical companies can reduce delays and speed up the production cycles without compromising product quality. This faster production timeline is particularly beneficial in the Saudi Arabian market, where the pharmaceutical sector is expanding rapidly, driven by government initiatives like Vision 2030. Companies that embrace automation can meet growing market demand while maintaining high quality and compliance standards.

Automation in pharmaceutical quality management also plays a significant role in reducing operational costs. Traditional manual systems require substantial human resources, leading to higher labor costs. Additionally, inefficiencies in manual processes often result in increased operational expenses, such as longer production times, rework, and handling of quality issues that arise from human error. Automating key quality management processes—such as inspections, compliance checks, and data validation—helps pharmaceutical companies in Saudi Arabia optimize their resources. With fewer manual interventions required, companies can allocate human capital to higher-value tasks, like strategic decision-making or process improvement, while allowing automated systems to handle routine tasks. This shift not only reduces labor costs but also enhances the overall cost-effectiveness of quality management processes. In an environment as tightly regulated as the pharmaceutical industry, consistency and standardization are vital for maintaining product quality and regulatory compliance. Automation facilitates standardized procedures for every step in the production and quality control process, ensuring that quality checks are consistently performed according to the same set of criteria across all production batches. This standardization reduces the likelihood of deviations and ensures that products meet predefined specifications every time. Automated systems can track and enforce standard operating procedures (SOPs) more effectively than manual systems, ensuring that all aspects of production, from raw material handling to final product inspection, adhere to strict quality standards. For pharmaceutical companies in Saudi Arabia, this level of consistency is critical in meeting both local and international regulatory requirements, such as those set by the Saudi Food and Drug Authority (SFDA) and international agencies like the US FDA and EMA. The demand for automation in PQMS is also driven by the need for real-time monitoring and faster decision-making capabilities. In traditional quality management processes, any deviations or issues are often detected only after the fact, leading to delays and costly corrective actions. Automated systems provide continuous, real-time data monitoring throughout the manufacturing process, enabling quality control teams to detect and address any issues as they arise. With automated data collection and analysis, decision-makers have immediate access to actionable insights that can help identify quality issues, compliance risks, or inefficiencies in production. This immediate feedback allows pharmaceutical companies to make more informed, timely decisions, ensuring the smooth operation of the production line and preventing costly disruptions. Real-time monitoring capabilities also enhance the ability to predict potential quality issues before they escalate, further reducing operational risks and improving overall efficiency.

Industry Expansion and Vision 2030

The expansion of the pharmaceutical industry in Saudi Arabia, combined with the strategic initiatives outlined in Vision 2030, is a powerful catalyst for the growth of the Pharmaceutical Quality Management Software (PQMS) market. Launched in 2016, Saudi Arabia's Vision 2030 aims to transform the healthcare sector by enhancing service accessibility, quality, and disease prevention. The Health Sector Transformation Program is centered on modernizing healthcare infrastructure, strengthening the workforce, and integrating advanced technologies to drive improvement. Saudi Arabia is investing heavily in developing its pharmaceutical industry to become a major player in the global market. The goal is to increase the local production of pharmaceuticals, reduce dependency on imports, and ensure that products meet global quality standards. This growing focus on domestic pharmaceutical manufacturing directly increases the demand for sophisticated quality management systems that can guarantee product quality, safety, and compliance with international regulations. With the expansion of pharmaceutical manufacturing operations, Saudi companies are required to scale their quality management processes, leading to a greater need for PQMS solutions that can handle larger volumes of production and ensure consistent quality across different manufacturing lines. As local pharmaceutical companies strive to meet the growing demand for high-quality medicines, PQMS plays a critical role in ensuring that manufacturing processes are streamlined, risks are minimized, and regulatory standards are met.

Vision 2030 places a strong emphasis on aligning Saudi Arabia's healthcare and pharmaceutical sectors with international standards. This includes adopting practices that meet global regulatory requirements, such as those set by the US FDA, the European Medicines Agency (EMA), and the World Health Organization (WHO). As Saudi pharmaceutical companies expand their operations and aim for international market entry, they must comply with strict regulatory frameworks that demand high levels of transparency, traceability, and product quality. The adoption of PQMS solutions is essential in helping companies adhere to these rigorous standards. These software systems automate processes such as batch tracking, product testing, documentation, and reporting, ensuring that companies can easily comply with both local and international regulatory requirements. As the pharmaceutical industry in Saudi Arabia continues to expand and diversify, the need for robust PQMS solutions to support regulatory compliance becomes more critical, driving market growth. As part of the Vision 2030 initiative, Saudi Arabia is making substantial investments in healthcare infrastructure, including the construction of new hospitals, research facilities, and pharmaceutical manufacturing plants. These investments are expected to lead to an increase in both the production and distribution of pharmaceutical products. In parallel, there is a growing demand for state-of-the-art technology solutions to manage the

complexities of pharmaceutical production and ensure that quality standards are upheld. The expansion of the healthcare sector under Vision 2030 requires scalable, efficient, and automated systems to manage quality across various stages of pharmaceutical production—from research and development to manufacturing and distribution. PQMS solutions are integral to supporting this expansion, providing companies with the tools they need to monitor quality, manage risk, and maintain consistency as production volumes rise. As the Saudi pharmaceutical sector grows, PQMS adoption will become a critical factor in ensuring that the industry remains competitive and compliant with global standards.

One of the key objectives of Vision 2030 is to increase the diversification of Saudi exports, including pharmaceutical products. The government aims to position Saudi Arabia as a leading pharmaceutical exporter in the Middle East and beyond. To achieve this, local pharmaceutical manufacturers must not only meet domestic demand but also ensure that their products meet international quality standards to access global markets. To succeed in these export markets, Saudi pharmaceutical companies need to adopt advanced quality management solutions that ensure their products are consistently produced according to the highest quality standards. PQMS solutions support this by streamlining production processes, improving product traceability, and ensuring compliance with international regulatory requirements. By investing in PQMS, pharmaceutical manufacturers can position themselves to capture new export opportunities and gain a competitive edge in the global market. Vision 2030 emphasizes innovation as a key driver of economic diversification, with particular focus on the healthcare and pharmaceutical sectors. As part of this effort, Saudi Arabia is increasing investments in pharmaceutical research and development (R&D) to foster innovation in drug development, vaccine production, and the creation of novel therapeutic products. This drive for innovation results in the need for high-quality, reliable management systems that can support the complex processes involved in R&D and ensure that new products meet safety and efficacy standards. With pharmaceutical companies investing in R&D to develop new medicines, the need for advanced PQMS solutions to manage the quality of research processes, clinical trials, and product testing becomes even more critical. PQMS platforms facilitate data integrity, audit trails, and compliance with regulatory requirements, ensuring that the entire R&D lifecycle adheres to the highest quality standards. As Saudi pharmaceutical companies push the boundaries of innovation, the demand for PQMS solutions to manage these processes will continue to grow.

Key Market Challenges

Regulatory Complexity and Compliance Requirements

The pharmaceutical industry in Saudi Arabia is heavily regulated, with stringent requirements set by the Saudi Food and Drug Authority (SFDA) and other international regulatory bodies. While these regulations are essential for ensuring product safety and efficacy, they also create significant challenges for pharmaceutical companies looking to implement Pharmaceutical Quality Management Software (PQMS) solutions.

The complexity of regulatory frameworks means that PQMS solutions must be highly adaptable and capable of accommodating various compliance standards, such as those from the US FDA, the European Medicines Agency (EMA), and other regional or global authorities. The need to meet multiple, often shifting, regulatory requirements increases the complexity of software systems, which can delay their adoption or raise concerns regarding their capability to ensure compliance across all regulatory environments. For pharmaceutical companies, integrating a PQMS that ensures ongoing adherence to local and international standards requires significant investment in customization and regular updates to stay in line with evolving regulatory changes. Companies that are not fully equipped to address these regulatory nuances may face delays in product launches or compliance issues that could lead to penalties, further complicating the market's growth.

High Implementation and Maintenance Costs

Implementing and maintaining a sophisticated PQMS solution can be financially burdensome, especially for small to medium-sized pharmaceutical companies. These systems require significant initial investments in software acquisition, customization, training, and integration with existing enterprise systems (such as Enterprise Resource Planning or Manufacturing Execution Systems). For many companies, these upfront costs can be a major deterrent, especially when they are already managing the expenses associated with R&D, production, and compliance.

The ongoing costs associated with the maintenance and updating of PQMS software add another layer of financial strain. Regular updates to accommodate regulatory changes, the addition of new features, and technical support all require additional investments. For smaller players in the pharmaceutical sector or companies that are just starting to embrace digital transformation, these financial barriers can make the adoption of PQMS less attractive, limiting the overall growth potential of the market. The high costs of implementation and long-term maintenance may cause companies to delay the adoption of digital solutions, relying instead on legacy manual systems that

are less efficient and more prone to errors. This reluctance to invest in advanced technology impedes the overall expansion of the PQMS market in Saudi Arabia.

Key Market Trends

Cloud-Based PQMS Solutions and Enhanced Scalability

The adoption of cloud-based technologies is a significant trend in the Saudi Arabian pharmaceutical industry, particularly for Quality Management Software (QMS). As the pharmaceutical sector expands, there is an increasing demand for scalable, flexible, and cost-effective solutions to handle growing production volumes and more complex regulatory requirements. Cloud-based PQMS offers these advantages by providing a centralized platform that can be accessed remotely, facilitating real-time monitoring, collaboration, and decision-making.

Cloud solutions also support seamless integration with other digital systems, such as Enterprise Resource Planning (ERP) and Manufacturing Execution Systems (MES), which is essential for ensuring comprehensive quality management across the entire production process. As pharmaceutical companies in Saudi Arabia embrace digital transformation, the demand for cloud-based PQMS is expected to rise, enabling companies to scale their operations without the constraints of traditional, on-premise systems. The ability to store vast amounts of data securely and access it from anywhere at any time further enhances operational flexibility, which is crucial for companies expanding their production capacity and meeting international market demands. Cloud-based solutions typically offer lower initial capital investment, reduced IT maintenance costs, and faster implementation times, which makes them more attractive to smaller and mid-sized pharmaceutical companies looking to modernize their quality management processes. This trend toward cloud adoption will likely drive increased market penetration for PQMS in the coming years.

Artificial Intelligence (AI) and Machine Learning (ML) Integration for Predictive Analytics

The integration of Artificial Intelligence (AI) and Machine Learning (ML) into PQMS solutions is another key trend that will propel the growth of the market in Saudi Arabia. AI and ML technologies allow pharmaceutical companies to harness vast amounts of data generated during the production process to identify patterns, predict potential quality issues, and recommend corrective actions before problems arise. This predictive capability is transforming the traditional approach to quality management, which has typically been reactive and based on post-production testing.

By leveraging AI and ML, PQMS systems can proactively monitor production processes in real-time, continuously analyzing data from sensors, inspections, and tests to predict deviations from predefined quality standards. This enables pharmaceutical companies to prevent defects before they occur, rather than relying solely on after-the-fact quality control. For example, predictive models can identify subtle trends in production data that might indicate future compliance issues, allowing manufacturers to take preemptive measures that reduce waste, downtime, and non-conformance events. In Saudi Arabia, where the pharmaceutical sector is striving for both international competitiveness and stringent local compliance standards, the integration of AI and ML into PQMS can significantly improve both product quality and operational efficiency. These technologies enable continuous process optimization, helping companies reduce costs, improve product consistency, and meet regulatory requirements more effectively.

Segmental Insights

Application Insights

Based on the category of Application, the Data Management segment emerged as the dominant in the Saudi Arabia Pharmaceutical Quality Management Software market in 2024. The pharmaceutical industry in Saudi Arabia, like elsewhere, generates vast amounts of data throughout the entire product lifecycle, from research and development (R&D) to manufacturing, testing, packaging, and distribution. This data includes raw material specifications, batch records, laboratory test results, production logs, and regulatory documentation. Managing this data manually or through outdated systems can lead to inefficiencies, errors, and non-compliance with regulatory standards. Data management within PQMS offers a structured, automated way to capture, store, and retrieve this critical data, ensuring it is accurate, consistent, and accessible in real time. As the pharmaceutical sector grows in Saudi Arabia, the volume and complexity of this data continue to increase, making it impossible for traditional methods to keep up. Companies need more sophisticated systems capable of handling large datasets while maintaining their integrity and traceability. The data management capabilities offered by PQMS solutions meet this demand by centralizing all quality-related data in a single platform, simplifying access, and streamlining data retrieval processes for analysis or compliance audits.

One of the primary drivers of the data management segment's dominance in the Saudi PQMS market is the increasingly complex regulatory environment. Saudi Arabia's pharmaceutical industry is subject to strict regulations imposed by both local authorities

like the Saudi Food and Drug Authority (SFDA) and international regulatory bodies such as the US FDA and the European Medicines Agency (EMA). These regulations mandate rigorous documentation of manufacturing processes, product testing, quality control measures, and distribution practices to ensure product safety and efficacy. Data management systems within PQMS are designed to help pharmaceutical companies meet these stringent compliance requirements. They facilitate the proper storage, organization, and retrieval of critical data that is required for regulatory audits, inspections, and reporting. The ability to maintain a robust, tamper-proof audit trail is crucial in the pharmaceutical industry, and PQMS solutions equipped with data management features provide automated tools for generating reports, tracking data changes, and ensuring all records are up to date and compliant with industry standards. The Saudi pharmaceutical industry's increasing emphasis on quality and compliance, particularly under Vision 2030, makes data management solutions essential. The ability to easily manage and track compliance-related data ensures that companies can avoid costly penalties or production delays caused by non-compliance. These factors are expected to drive the growth of this segment.

Regional Insights

Northern & Central Region emerged as the dominant in the Saudi Arabia Pharmaceutical Quality Management Software market in 2024, holding the largest market share in terms of value. The Northern and Central regions of Saudi Arabia are home to some of the largest pharmaceutical manufacturers and distributors in the country. Riyadh, the capital, serves as the center for many of the nation's leading pharmaceutical companies, while Jeddah, located on the western coast, is a key hub for logistics and distribution. Dammam, in the Eastern Province, is another important industrial city that hosts several pharmaceutical companies.

These regions' dominance in pharmaceutical manufacturing and distribution plays a critical role in the adoption of PQMS. As pharmaceutical companies in these areas scale their operations and expand production capacity to meet growing demand, they require robust quality management systems to ensure product consistency, regulatory compliance, and operational efficiency. The increased volume of production and distribution necessitates the use of advanced software solutions to manage quality across multiple processes, making PQMS a critical investment for companies in the Northern and Central regions. Additionally, these areas host a high concentration of research and development (R&D) activities in the pharmaceutical sector, driving the need for sophisticated data management and quality control systems. As companies aim to improve product formulations, accelerate time-to-market, and ensure compliance

with stringent regulatory requirements, the demand for PQMS solutions in these regions is further amplified. The Saudi Food and Drug Authority (SFDA) and other key regulatory agencies responsible for pharmaceutical standards and quality control are located in Riyadh, which is in the Central region of the country. Being in close proximity to these regulatory bodies allows pharmaceutical companies in the Northern and Central regions to stay abreast of the latest industry regulations, compliance standards, and safety protocols. This close proximity also ensures easier communication between regulatory bodies and pharmaceutical companies, helping to facilitate smoother interactions, inspections, and approvals. As pharmaceutical companies in these regions must comply with rigorous local and international standards set by the SFDA, the US FDA, and the European Medicines Agency (EMA), PQMS becomes essential for ensuring that all manufacturing processes, product testing, and documentation are consistently aligned with these regulations. The need for real-time data management, traceability, and reporting within these regions drives the demand for PQMS solutions that can streamline compliance processes and improve quality assurance. The proximity to regulatory bodies in these regions enables pharmaceutical companies to implement PQMS systems more efficiently, ensuring that quality management processes are always up to date with the latest regulatory requirements. This makes the Central and Northern regions more attractive for the implementation of PQMS technologies, contributing to their dominance in the market.

Key Market Players

MasterControl Solutions, Inc.

AmpleLogic

Pilgrim (IQVIA)

Sparta Systems

Dassault Syst?mes

Veeva Systems Inc.

Ideagen

Report Scope:

Saudi Arabia Pharmaceutical Quality Management Software Market By Application (Data Management, Training manag...

In this report, the Saudi Arabia Pharmaceutical Quality Management Software Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Saudi Arabia Pharmaceutical Quality Management Software Market, By Application:

Data Management

Training management

Supplier management

Regulatory and Compliance Management

Corrective Action Preventive Action (CAPA) Management

Audit Management

Change Management

Non-Conformances Management

Inspection Management

Risk Management

Others

Saudi Arabia Pharmaceutical Quality Management Software Market, By Deployment:

Cloud-based & Web-Based

On-premises

Saudi Arabia Pharmaceutical Quality Management Software Market, By Region:

Eastern

Western

Northern & Central

Southern

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Saudi Arabia Pharmaceutical Quality Management Software Market.

Available Customizations:

Saudi Arabia Pharmaceutical Quality Management Software market report with the given market data, TechSci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

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