

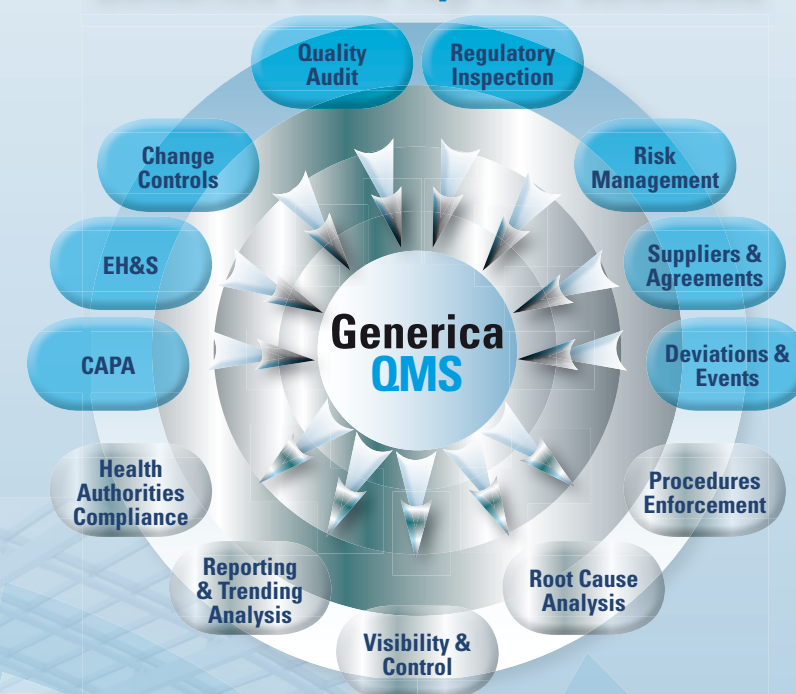
Generica QMS

End to End QUALITY Management Solutions

KCS QMS Software Solutions, Generica, is a unique technology platform, allowing companies to conduct a full quality life cycle management, encouraging them to improve their quality and compliance by harmonizing all processes under one global system.

Generica allows its users to work via an intuitive and simple integration with **Microsoft Office tools**, thus offering a fully configurable, user-friendly and automated workflow management system, which diminishes the learning curve of the system to a minimum, saves time and resources, and reduces quality risks.

Generica QMS Top Tier solutions



**Improve Quality, Ensure Compliance,
Harmonize Processes**

About KCS

KCS offers end-to-end Quality Management and GRC Management solutions for highly regulated industries, such as life science, finance, and insurance. Through its flagship solution platform - Generica - the company allows its users to manage and improve their internal processes, while ensuring compliance with relevant requirements and standards of both local and global authorities.

Based in one of Israel's well-known IT R&D centers, KCS gained throughout the years an impressive client base of leading global healthcare and pharmaceutical companies, well known financial institutes and large public corporates. It offers its clients a highly professional and experienced team of system integrators, technology development experts, and software designers, all dedicated at bringing the best practices and top-notch technology to their clients.



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Generica QMS

Generica QMS Modules

Quality Audit Management

Offering efficient management of audit records data, meeting audits scheduling and planning requirements, addressing all quality audit management challenges, such as audit planning and conflict resolution, participant confirmation, audit preparation, audit conducting, observations and CAPAs remediation, auditor's skills management, resources management etc. Generica QMS offline tool for auditors ensures comprehensive tracking of audit processes by enabling easy management of all actionable information and critical processes.

Regulatory Inspection

Allowing upload and management of all internal inspection data and performing gap analysis across the organization. Generica QMS Regulatory Inspection module facilitates the management, sharing, checking and remediating of inspection findings across the organization. The module includes a powerful statistics and trend analysis tool for smart and efficient management of inspection information.

Quality Risk Assessment

Analyzing corporate risk factors and presenting the risks in a clear and action-ready format. Generica QMS Risk Assessment module is based on internal audit results, current year audit planning, inspection results and manufacturer properties. This module assists the corporate quality team to better plan, conduct and analyze quality activities; senior managers can view a scoreboard that covers the organization's quality areas and consistently provides an accurate quality risk picture.

Supplier and Quality Agreements

Managing global supplier audits to allow more efficient monitoring of suppliers across sites, while improving supplier-related quality processes, and saving time and effort. Generica QMS Supplier and Quality Agreements module addresses challenges such as potential supplier inspection, supplier quality and approval process, agreement management, as well as external supplier audit planning and execution. This module assists the quality team in ensuring a valid and up-to-date agreement for each product and each supplier, as well as controlling individual suppliers while maintaining a global perspective.

Deviations and Events

Providing a secure and reliable system for tracking and reporting deviation and event records in accordance with current Good Clinical / Laboratory / Manufacturing / Pharmaceutical Practice. Generica QMS Deviations and Events module allows its users to analyze previous problems and identify opportunities for quality improvement, all effectively managed on a global scale to ensure company-wide regulatory compliance.

CAPA Management

Offering comprehensive CAPA management with flexibility to allow for the implementation of a CAPA process in each relevant business unit in the organization. With CAPA being a crucial process to an effective quality management system, Generica QMS CAPA Management module allows its users to efficiently handle such processes, including Customer Complaints, Deviations, Safety Incidents, Audit Observations, Change Requests and Action Items, Environmental Incidents and more, from initiation of a new record, through the approved investigation process and all the way to root cause analysis, CAPAs management and QA deviation resolution.

EH&S Management

Efficient capturing and tracking of all Environmental, Health and Safety (EH&S) issues, including incidents impact, potential injuries, regulatory commitments, CAPAs etc. Generica QMS EH&S Management module provides easy and intuitive reporting capabilities of the issues and their prevention plans according to relevant government or local authority agencies requirements.

Change Control Management

Ensuring smooth implementation of Change Control processes to assist the organization in management of records from submission through implementation, verification and control, according to its standards and procedures. Generica QMS Change Control Management module provides effective management of changes in documents, hardware, software, processes, engineering, facilities, machinery, equipment, IT and other areas. It assists in improving change process efficiency and helps ensuring compliance across the organization's departments.

Why Generica QMS?

Adaptability and Smooth Global Management of All Quality Processes

Generica QMS solution efficiently centralizes and automates the quality processes across the enterprise, allowing authorized users to initiate any quality records via a user friendly data entry web forms, linking them to any quality records in the centralized database, thus providing direct access to all background information and critical data.

Flexible and Quick Configuration and Deployment

Generica QMS solution is a fully configurable software platform, allowing companies to easily implement their specific business processes with minimal use of time and resources, while retaining full quality and compliance requirements. Following a short phase of prototyping all quality processes, design and configuration, the solution is ready for deployment, validation and training.

Constant Improvement by Execution with Checklists and History

Generica QMS solution offers the use of databases with both universal controls, such as FDA and CE, as well as internal SOP controls for conducting audits. Every quality step starts with historical content and up-to-date checklists, ensuring constant improvement of the quality processes by covering all past fails and requested areas.

Strong Tracking and Reporting Capabilities

Progress and results of every case handled within any module can be easily tracked with Generica QMS solution in real time. With its automated reporting capabilities and enhanced dashboards Generica QMS facilitates annual project planning, resource allocation, budget vs. actual reporting, advanced trend analysis, and much more. Generica QMS solution offers simple tracking of response status to significantly reduce project completion time and diminish the possibility for quality gaps and risks.

Ease of Use

Generica QMS solution allows users to conduct and manage quality processes through seamless integration with Microsoft Office tools. This unique ability ensures no duplication of efforts: all notes, reviews, procedures, responses and reports can be made in the original documents. By maintaining process templates for key organizational processes, the system enables single-click inclusion of all up-to-date information.

Generica QMS Unique Features & Benefits

- A single, centralized, web based application to manage all QMS needs
- Intuitive web interface and dashboards
- Flexible and fully configurable to user specifications
- Enhanced workflow management via workflow engine with automation rules, alerts and escalation
- Easy-to-use Microsoft Office integration
- State-of-the-art offline audit tools and questionnaires
- Outstanding query capabilities - graphic presentation of saved queries results
- Advanced reporting, including graphic presentation of reports
- Mobile devices accessibility
- Integrated Business Intelligence (BI) capabilities
- Internal Document Management platform to ensure adherence to organization SOPs
- Web services / API integration

Generica QMS can be configured to suit the user requirements and specifications, or implemented in the organization via pre-packaged solutions.