

GRC Solution Suite

Audit & Inspection Manager



EQMS Audit & Inspection Manager saves you time and money by allowing you to plan, schedule and manage multiple audits quickly and efficiently

EQMS reduces the compliance burden associated with Standards and Regulations.



9001, 14001,
22000, 27001,
31001, 45001,
TS 16949





HIGHLIGHTS

- Plan and Schedule**
 EQMS Audit & Inspection Manager schedules and plans work, setting milestone dates and automating recurring activity.
- Create Templates**
 EQMS Audit & Inspection Manager stores audit and inspection templates for reuse, facilitating standardisation and benchmarking.
- Activity at a Glance**
 View the entire audit and inspection program by year/month/week. Filter the audit calendar to get straight to the information you need.
- Questions and Checklists**
 Draw questions from your question bank and organise into checklists to eliminate rework. Specify question response format to validate input.
- Categorise Audits/Inspections**
 Create your own classification of audit and inspection data, speeding up location, retrieval and analysis of information.
- Alerts and Notifications**
 EQMS Audit & Inspection Manager emails CAPA and escalation tasks to assure timely completion of remediation activity.
- Online or Offline Data Input**
 Supply audit and inspection data offline on your mobile device or exported spreadsheet and sync on return to your office.

Verify Compliance and De-Risk your Organisation

Organisations must comply with a host of regulatory and business standards to compete in the global marketplace. Comprehensive audits and inspections are essential to verify and demonstrate compliance and, critically, to reduce risk. A regular and effective internal audit and inspection process ensures that management, employees, customers and your regulators have confidence in your business processes.

However, audit/inspection management is becoming increasingly challenging. Complex businesses are mandated to conduct a huge volume and vast array of different types of audit and inspection. Spreadsheets and simple point solutions are incapable of managing the programme, particularly if it takes place across multiple sites and geographic boundaries.

The greater volume of audit activity, the greater the danger that the audit and inspection process all too often creates a significant overhead without contributing to business improvement. The inspection is completed but the work to rectify problems is often neglected or forgotten, perpetuating error and introducing risk. The absence of a systematic and robust internal audit process is the oft-cited common denominator of high profile business failures. This absence was highlighted as a key factor in the 2008 global banking crisis.

An Introduction to EQMS Audit & Inspection Manager

EQMS Audit & Inspection Manager helps you manage your audit and inspection processes in a single, comprehensive framework. It simplifies the planning and running of any type of audit or inspection, including internal audits, operational inspections, IT audits, supplier audits, safety inspections, environmental audits and quality audits. This includes the planning and scheduling of audits and inspections, the development of repeatable checklists of questions and field data collection. You define the audit reporting required, and register findings within audits for review by auditees and Management. Workflow-enabled functionality automates corrective actions derived from the findings.

EQMS Audit & Inspection Manager minimises the cost of audit and inspection, and extensive management reports build a platform for business improvement. Advanced functions such as configurable remediation workflows, time tracking, email-based notifications and checklist completion allow organisations to implement industry best practices.



HIGHLIGHTS

Benefits that Deliver Competitive Advantage

EQMS Audit & Inspection Manager saves you time and money by allowing you to plan, schedule and manage audits quickly and efficiently. Workflow-enabled functionality guides you through the full audit process, guaranteeing completion of any corrective or preventive actions and storing evidence of compliance.

EQMS Audit & Inspection Manager helps you eliminate process issues quickly and painlessly. It delivers a range of benefits:

- Configurable Workflow**
 Automated workflows drive remediation activity using your existing processes for investigation and root cause analysis.
- Integration**
 EQMS Audit & Inspection Manager integrates with all EQMS modules and Mobile Phone/Tablet technology to maximise accessibility.
- Management Information**
 A customisable dashboard and report suite provide all your audit and inspection metrics. Instantly generate your own reports in MS Word, MS Excel, and Adobe PDF.

- ✓ Reduce risk and eliminate error
- ✓ Rapidly resolve problems with closed-loop processes for recording findings, developing recommendations, and implementing action plans
- ✓ Reinforce best practice through continuous review and improvement
- ✓ Standardise data collection to eliminate audit errors and inconsistencies
- ✓ Real-time audit analysis improves decision-making and performance
- ✓ Maximise visibility of audit processes and metrics delivers better risk management and compliance
- ✓ Minimise the effort required to audit across multiple standards & regulations, geographic territories and organisational boundaries
- ✓ Cut audit costs and maximise the ROI of your mandatory audit activity
- ✓ Improve the confidence of staff, customers, partners and regulators in your processes

Audit List CMI 11

Audit Details Questionnaire Findings

Audit: Clinical Material Inspection m

Reference: CMI 11 * Audit Owner: Clarke, Fiona *
 Title: Clinical Material Inspection * Status: Ongoing
 Audit Type: A10 Clinical Material Start Date: 21 October 2015
 Report Agreed Date: Publish Date:
 Finish Date: Closed Date: 01 December 2015
 Scope: This procedure compiles the main aspects that are to be verified at a clinical laboratory during a GCP inspection requested by the EMEA. * Comments: This procedure applies to EMEA, EU/EEA Inspectorates.
 Expected Duration:

Associated Items Auditors and Viewers Audit Scores

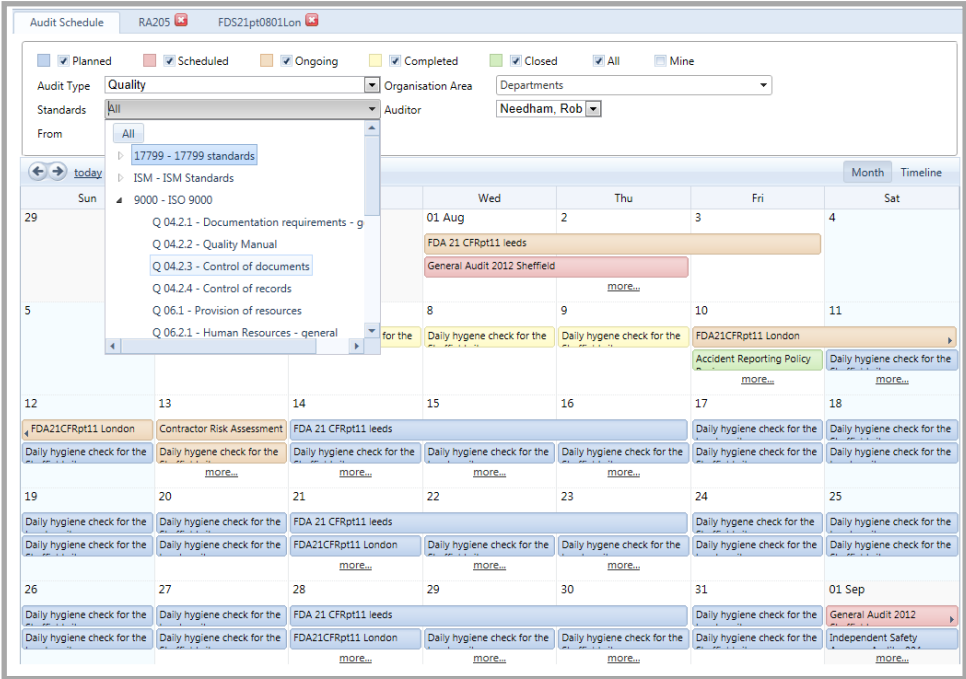
Associated Items

Code	Title
Organisational Areas	
Standards	
Documents	

Features & Benefits

Plan & Schedule

EQMS Audit & Inspection Manager allows you to systematically organise a complex programme of audit activity quickly, cost-effectively and painlessly. Authorised users schedule and plan audits and inspections, set milestone dates and automatically calendar recurring activity. EQMS Audit & Inspection Manager allows you to manage any type of audit or inspection, defining scope, recording milestone dates and results.



Audits are linked to territories, business units, departments, products, processes, specific document sets and/or particular standards, for subsequent enquiry and analysis. Visibility of audit information is only available to authorised users and/or groups of users. Your template audit checklists and reports are stored in a library and attached to each audit for completion with clear evaluation and pass/fail criteria. The system stores training records and contact details of your auditors who are assigned to each audit by a Manager who selects from the list of auditors based on availability and their record of current and past audit experience.

Calendar

The user sees a filterable calendar view of all audits held in the system. A daily, weekly and monthly view is available with views restricted depending on the user's permissions. From a list of the audit records the user is entitled to see, he/she is able to filter by status – planned, scheduled, ongoing, completed closed; by type of audit; by department; by standard or regulation; by auditor – or any combination of the above filters to drill into the data you require. Audits or inspections are scheduled periodically or triggered on an ad-hoc basis with due dates set and automatically notified to auditees and the auditor.

Templates

EQMS Audit & Inspection Manager allows you to create and store audit templates for each type of audit or inspection you carry out. This ensures all audit activity is standardised and comprehensive. Use of the templates ensures that only accurate data is

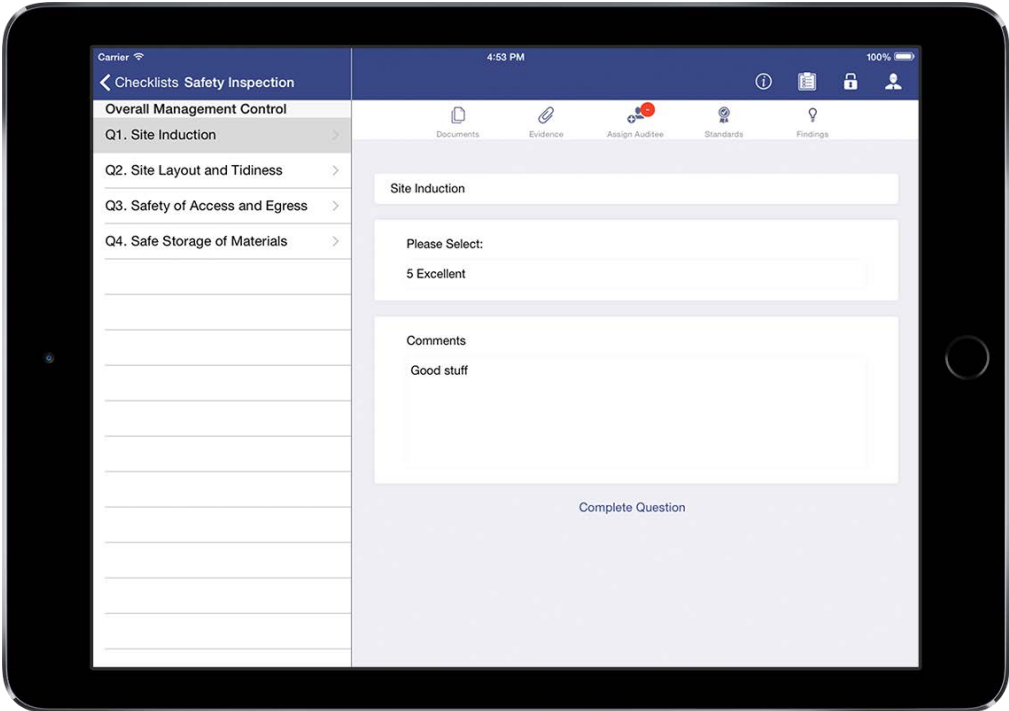
collected. This in turn produces meaningful metrics that track KPI performance over time. Your audit and inspection questions are stored in a question bank allowing you to draw questions with ease from the bank to organise into checklists, thus eliminating duplication of effort and rework. You easily link audit activity to regulations or standards to provide instant access to evidence of compliance.

Questions & Checklists

You store all audit and inspection questions in a bank, specifying any required data by label and type (dropdowns, numbers, dates, text, Yes/No). You compile your questions into checklists using a simple add/remove step. There is no restriction on the number of checklists you associate with each type of audit or inspection. Questions can be made mandatory or optional as required.

EQMS Audit & Inspection Manager allocates questions to individual auditors for response.

Question Response



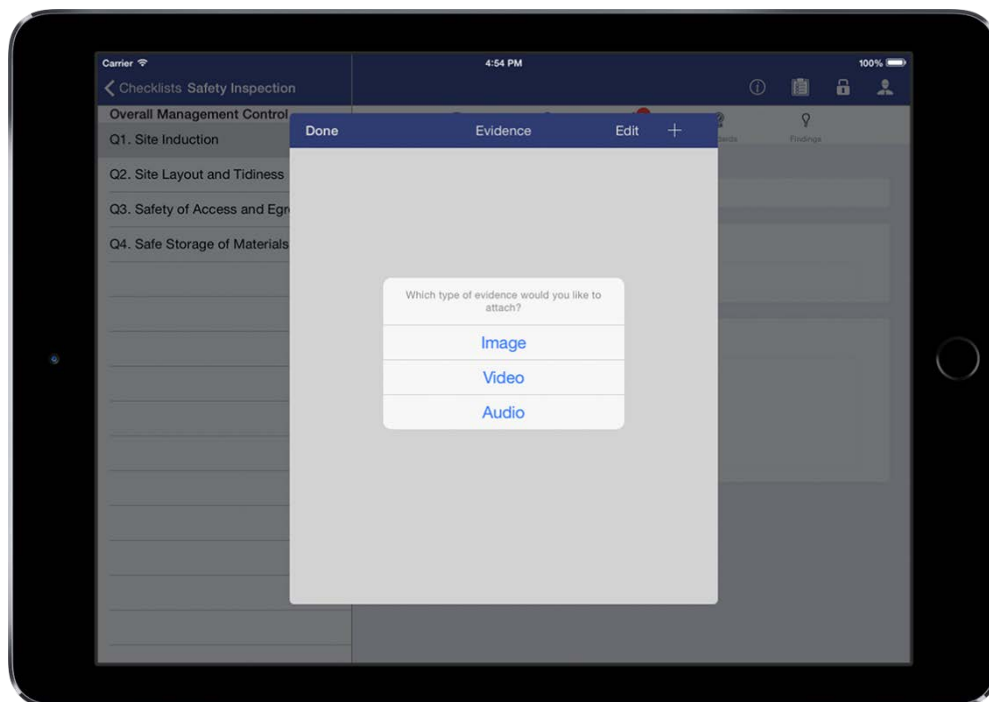
An individual audit or inspection can consist of several checklists of questions with each checklist assigned to the appropriate auditor. Question response and evaluation criteria are in your pre-defined format to underpin accuracy and responses automatically trigger the raising of non-conformances so problems are never ignored. The system will also drive notification of reportable issues to the relevant authorities. EQMS Audit & Inspection Manager tracks the status of the audit, and measures its progress against milestones dates to ensure timely completion.

Offline Sync

EQMS Audit & Inspection Manager allows you to record audit and inspection data offline on your mobile device or exported spreadsheet and sync on return to your office. This means you are able to carry out audits or inspections on-site without access to the corporate network. You then synchronize the data with main system when you regain network access. This is perfect for organisations with a mobile workforce that want to optimise audit efficiency when working at a supplier, customer or partner site or a remote location.

Evidence

Documents and photos in any format, such as Adobe PDF, MS Word, MS Excel, can be attached at any stage of the audit or inspection as supporting evidence.



All attachments are centrally stored for ease of access.

CAPA Workflow & Escalation

Audit findings and follow-up actions are recorded in the system and must be completed to close out an audit. Actions are automatically routed to an owner via the system and by email and may form part of your process methodology for addressing problems (5 Whys, Root Cause Analysis, etc)). The status of any action is visible and reported on by the system. If required, the Audit Manager can introduce escalation routines to ensure the completion of critical activity within defined timescales. The auditor or inspector is able to record as many findings as necessary against each audit and assign as many actions by as many users as required to address or avoid problems. The system provides managers with a view of all CAPA activity at a glance to check progress. This view is filterable by status – outstanding or completed – and the manager can drill down into problem areas.

Audits, Audit Findings & CAPA Categorisation

EQMS Audit & Inspection Manager allows you to categorise your audit types (health and safety, environmental, supplier etc), auditor types (internal, external, supplier, customer etc) and log the standards you are measured against. The system is flexible and holds details of any standard. If the standard itself is published on the Internet a hotlink provides immediate access to the current version. EQMS Audit & Inspection allows you to create your own fields for categorising Audits, Audit Findings and CAPA. You can create fields that require date, text, numeric values, simple yes or no responses, or a combination of these. This means that you can record precisely the data that you need based on your existing audit processes and audit checklists. The categorisation of audits and inspections drives the outputs and ensures the quality and usefulness of system reports. Over time, patterns and trends will emerge that guide the process of business improvement.

Risk Assessment

EQMS Audit & Inspection Manager integrates with our Risk Manager module to support risk assessments based on parameters such as the severity of the risk and likelihood of occurrence. Risks are assessed and computed based on configurable methodologies and algorithms, giving auditors a clear view into your organisation’s risk profile.

Security

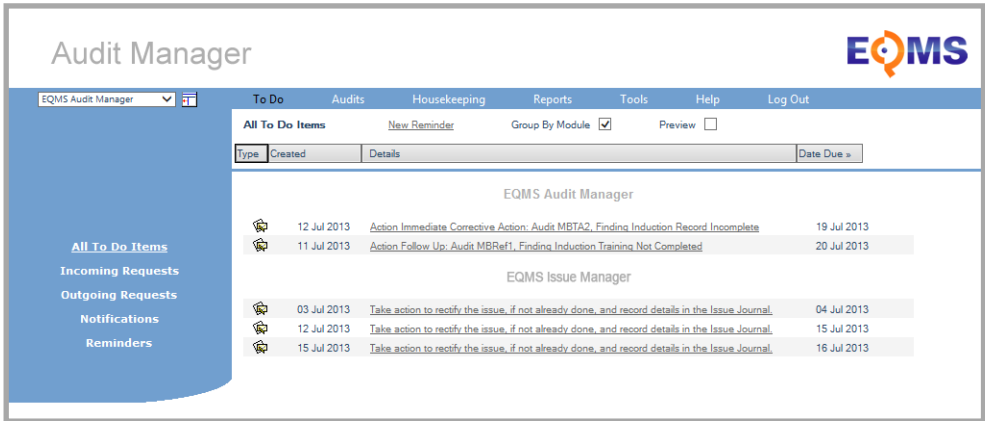
EQMS Audit and Inspection Manager incorporates controls that ensure clarity of responsibility and prevent unauthorised tampering. Security features allow you to present individually tailored views of audit details. Some audits may be visible to all users; some may be restricted to individuals or groups with appropriate permissions. You can devolve audit management responsibility to individuals or groups by giving them administrative access to the Audit & Inspection Manager module or limiting them with specific audit/inspection management privileges. Users will only be able to update or edit audits that you give them permission to. Those users, in turn, may devolve responsibility for elements of their audits to other individuals or groups. Such permissions include options for read only and the update of records.

History

Authorised managers have access to a complete audit trail of changes made to all records in EQMS Audit & Inspection Manager. This provides you with a complete historical record of change that provides a record of due diligence and compliance. You, your auditors and assessors have an easy-to-read view of changes made over the entire history of a record or over a chosen period of time. In addition, you are able to view how a given record looked at a particular point in time. This satisfies all regulatory demands for data integrity.

To Do List

EQMS Audit & Inspection Manager automatically generates messaging and/or e-mail prompting audit activity and corrective actions stored in the system.



Actions are triggered by dates and deadlines held in the Audit & Inspection Manager database and compliance with requests is analysed and reported.

Seamless Integration

EQMS Audit & Inspection Manager is integrated with all other EQMS modules, allowing you to see any associated risks, documents or issues linked to an audit. All messages triggered by Audit Manager for warning, advice or action are passed directly into your email system so as to automatically involve all of the required stakeholders. These can be accessed and responded to on a PC, laptop, mobile or tablet. To maximise the benefit of messaging, and support compliance, there are options to configure the frequency and number of reminders and define escalation routines. Your decision-making is always completely informed by all of the information at your organisation’s disposal. In addition, EQMS is complete with a set of web services that speed up the process of integration with a range of other commonly-used business applications to minimise the effort and cost of any bespoke integration requirement. Export EQMS audits to Microsoft Word and Excel for offline completion. Import audits in Excel and Word format into EQMS to avoid duplication of effort.

Embed compliance in the way your organisation operates, minimising error and reducing risk.

Dynamic Reporting & Metrics

EQMS reporting provides complete visibility of audit activity and actions to resolve problems and simplifies status tracking. Reports present complete traceability of records, making audit and inspection management a predictable and efficient process and maximising the likelihood of problem resolution. Graphical dashboards include drill-down capabilities to provide statistics and data to monitor task completion versus target.



Users gain access to all audit data and history as well as analyses of auditor performance and audit results. In addition to the standard reports available, you can build custom reports using the simple Reports Wizard. This allows you to export and manipulate screen data to a variety of standard file formats (PDF, Word, Excel, TIFF, CSV).

Tools & Help

Users have access to context-sensitive help screens and a range of system tools. The precise tool-set varies depending on the permissions of the user but includes the ability to view one’s own user details, and to broadcast messages to groups of colleagues. With one mouse-click, users can check on the status of the audit or inspection they are viewing.

Branding & Localisation

Add logos, colours, style sheets to ensure EQMS emulates the look and feel of your web presence, extranet or intranet. Localise EQMS by tailoring EQMS phrases and labels to match your organisation’s taxonomy. Add other EQMS language versions to support your users by eliminating language barriers.

Technical Flexibility

We offer EQMS on a SaaS basis with your users accessing your system via a secure https website. Alternatively, we install EQMS on your network integrating with your intranet, extranet or company portal as required. You choose the deployment option that best suits your organisation’s forward IT strategy.



You access EQMS Audit & Inspection Manager via your laptop or PC using any commonly-used web browser. You can also access EQMS Audit & Inspection Manager via your tablet or mobile phone providing complete accessibility on the move.



www.eqms.co.uk

Founded in March 1995, Qualsys Ltd is a leading provider of best-of-breed Governance, Risk and Compliance solutions that is privately owned, profitable and certified to ISO 9001/TICKIT and UKAS/ANSI RAB (certificate 1857/99).

Our flagship EQMS solutions help customers eradicate the compliance burden of a vast array of regulations and international standards such as ISO 9001, ISO 14001, ISO 27001, ISO 31000 and ISO 45001/OHSAS 18001. EQMS standardises processes, underpins corporate governance and provides a robust framework for managing risk. Our solutions drive down cost and deliver tangible competitive advantage - online or on-premise deployment combines with expert support and training to provide rapid return on investment. EQMS is used in over 100 countries worldwide across a range of business sectors from blue-chip organisations as diverse as Astra Zeneca, BT, Carillion and Diageo to smaller organisations committed to continuous quality improvement.



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