Abbreviated

**Request for Information**

**eQMS Project**

(Selection and Implementation of an electronic Quality Management System)

To send an RFI Request to Qualsys, email: help@qualsys.co.uk

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# Introduction

The objective of the eQMS Project is to establish a unified global eQMS at the customer’s site, which will be based on a joint understanding of globally applied definitions and processes in quality management. The eQMS is intended to support all different levels - global, divisional, regional and local operations - of the quality community at the customer.

The eQMS will be a globally used system, respecting the needs of all different business operations within the customer’s organisations. The new eQMS will be the standard software system for quality relevant processes. All existing local systems will ultimately be exchanged by the eQMS, respecting the individual necessity.

## Scope / Objectives

The scope and objectives of the eQMS project may be described in three dimensions:

1. **Geographic** –The eQMS solution will be accessible world-wide, from all sites within the customer’s organisation.
2. **Business Line** – In Scope of the eQMS project is the whole Global Quality Management and Global Quality Operations organization of the customer including global, divisional, regional and local operations.
* **Processes:** The following processes are in scope of the vendor selection process for the new eQMS:

*Priority 1* (Must be covered by the new selected vendor software):

* Deviations (Non conformities, Incidents, Excursions, Events, Audit Observations, OOS / OOT / OOL etc.)
* Change Management
* Actions (Corrections, Corrective- / Preventive- / Risk Control- / Change- / Other- / Actions)
* SOP Management (Document Management)

*Priority 2* (Could be covered by the new selected vendor software):

* Audit Management
* Root Cause Analysis
* Quality Risk Management
* Complaints Management

## Timing

The project is intended to run for a period of several years:

Phase 1

Stage 1 - 10/2013 – 05/2014 – Vendor Selection phase

 DATE Abbreviated RFI

 DATE RFI / Review answers and execute action plan

 DATE Proof of Concept / RFP

Phase 2

Stage 1 – DATES – Pilot / Limited Scope Implementation

Stage 2 – DATES – Start full Scope Implementation and Global Rollout

## Geographical spread

The intended scope is worldwide, with possible server hardware deployment.

## Estimate for number of users

* Contributor:
* Consumer:

# General Information

## Vendor Information

To qualify for the former RFI process at the customer, you have received this abbreviated RFI with several questions. After an analysis of your answers and a pre-selection of potential candidates, we will provide you a full RFI with more questions regarding your solution and your service capabilities.

Please provide the following information about your company.

### General Information

| **QuestionCode** | **Question** |
| --- | --- |
| **RFI-GI-001** | Main company business classification |
|  |  |
| **RFI-GI-014** | Countries you have offices in and where you operate |
|  |  |
| **RFI-GI-005** | Name of contact for any question regarding the request for information |
|  |  |

### Sales information

| **QuestionCode** | **Question** |
| --- | --- |
| **RFI-SI-003** | Do you use any commercial third party components in your core software offering?If yes, please state the number and kind of third party components. |
|  |  |
| **RFI-SI-010** | Number of current customers |
|  |  |
| **RFI-SI-011** | Number of current users - Total?- Average?- Maximum number of users in a single customer solution? |
|  |  |
| **RFI-SI-007** | Significant references – at least 5 – in our industry sector related to:- No of users- Geographic Spread - Functionalities covered - System integrated with - Comments |
| **RFI-LI-006** | Has your software development processes been audited before? This should include any third party components and / or subcontractors.If Yes, who performed the audits and have there been any deficiencies found? If Yes, which corrective actions were implemented? Provide the latest three results of the external audits done by your user groups. Additionally the vendor is at all times, during the term of the agreement, subjected to an audit by our company.Our company shall have the right to inspect or have inspected by an independent auditor all activities and/or services performed by the vendor and subcontractors (if any).The audit will be conducted in accordance with our company’s audit standards.In the case of subcontracted suppliers are used to provide some of the service required: • Our company reserves the right to audit the sub-contracted supplier(s) used by the vendor• The vendor can be required to audit subcontracted supplier(s).Please confirm this in your answer. |
| **RFI-LI-007** | Has your company and / or your software development any quality certificates like DIN EN ISO 9xxx, ISO 26262, DO-178B, ED-12B, IEC 61508, MISRA, FDA/IEC 62304, CENELEC, TCSEC, ITSEC, CC, LPI or others?  |

# Architecture

| **QuestionCode** | **Question** |
| --- | --- |
| **RFI-AI-001** | Provide information regarding the IT architecture of your proposed solution |
|  |  |
| **RFI-AI-002** | Provide information on scalability aspects of your proposed solution |
|  |  |
| **RFI-AI-006** | Provide information on client frontend user interface (web-based, fat client, multi-language capabilities…) |
|  |  |
| **RFI-AI-007** | What languages do you support with your software? - English- German- Chinese- French- Spanish- Arabic- Other |
|  |  |

# Consulting, Support

| **QuestionCode** | **Question** |
| --- | --- |
| **RFI-SE-001** | In which countries is support available? |
|  |  |
| **RFI-SE-002** | In which language(s) is the support available? |
|  |  |
| **RFI-SE-003** | Telephone hot-line availability - In which language? - Operating / Opening hours? |
|  |  |
| **RFI-SE-004** | Number of staff and where situated |
|  |  |
| **RFI-SE-005** | Number of calls / tickets received per month |
|  |  |
| **RFI-SE-008** | Problem solving management (Documentation, follow up, review by QA...)? |
|  |  |
| **RFI-SE-013** | Do you provide validation documentation support like: - Functional specifications?- Validation test scripts (IQ/OQ)?- Configuration and/or Customization documentation of your product?- Manual for interfacing with other products?- Others? |
|  |  |
| **RFI-SE-014** | Is your software compliant in regard to the following guidelines: - |
|  |  |

# Submission of Responses

Prior to the RFI answer deadline, MAIN5 is available to answer any complementary questions in order to clarify any point that needs clarification and help vendors to submit the best suited answers.

* All responses to this abbreviated RFI should be provided electronically in Microsoft Word Format not exceeding 20 pages in total.
* Proposals, deliverables and additional material must be provided in English.
* **Deadline** for responses is .
* Send all responses to: …
* If additional printed material is to be provided, please send it to the following:
* Please send any questions concerning this RFI to …. by the above email.

# References

|  |  |  |
| --- | --- | --- |
| **Document Code** | **Document Name** | Version |
|  |  |  |

# Glossary of terms

|  |  |
| --- | --- |
| **Abbreviation** | **Definition** |
| eQMS | Electronic Quality Management System |
| GMP | Good Manufacturing Practice |
| GQA | Global Quality Assurance |
| GQM | Global Quality Management |
| GxP | Common abbreviation for GMP and other guidelines |
| LIMS | Laboratory Information Management System |
| OOL | Out of Limit |
| OOS | Out of Specification |
| OOT | Out of Trend |
| QMS | Quality Management System |
| RFI | Request for Information |

**End of document.**