

Qualman Development Project

Group 27

Elena Malioutina, <elenamalioutina@hotmail.com>
Rahwa Tedros, <rahwa@hotmail.com>,
Kristen Kjellström, <kristerk@kth.se>,
Pia-Marie Jørgensen, <pia.jorgensen@bredband.net>

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Introduction

Pharmaceutical companies are required by authorities (e.g. the US Food and Drug Administration and the Swedish “Läkemedelsverket”) to perform careful testing and documentation of all equipment, processes, computer systems, methods etc. that are used to produce medicines. The products themselves are also subject to testing programmes. Basically, according to GMP – Good Manufacturing Practise, anything that can have a direct or indirect impact on patient safety must be tested and documented. Another basic principle is that if something has not been documented, it has not been performed (which causes some people to translate GMP as “Great Mountains of Paper”).

These processes of verification are all referred to as qualifications. If several qualifications are needed for an object, they are generally grouped into a validation. Examples of qualifications needed in one validation might be installation qualification (IQ; testing design requirements), operational qualification (OQ; testing functional requirements) and performance qualification (PQ; testing, as the name suggests, performance, i.e. non-functional requirements). All qualifications produce a number of documents. Contained in this document would be an example of one of them - the user requirements specification (URS).

The computer system described in this requirements document will be used for managing information about qualifications performed by a pharmaceutical company on products, processes, methods and equipment. The system will henceforth be referred to as “Qualman” (for Qualification Management). In addition to storing unique qualification numbers and information relating to these, the system will provide possibilities to search for and extract information to be presented to inspecting authorities. One example is information relating to the Validation Master Plan (VMP), which is a sort of overview of the validation status of the entire company.

The Qualman system will contain references to other company computer systems for e.g. change control, projects, equipment maintenance and instructions. It will however not presently have direct interfaces to these systems.

The system will be used mainly by members of the department “Validation”, charged with performing and supporting validation and qualification testing throughout the company. They will, on request, provide a unique qualification number to the designated qualification leader of a particular qualification. This department is also responsible for the archiving of all qualification documentation. In future, qualification leaders from other departments may be allowed to enter information into the system themselves, and read access will be granted to an even greater number of people. All personnel using the system will however receive documented training before being allowed access (another principle of GMP).

The present system used for qualification management within the company has limitations in terms of storage possibilities. It does also not sufficiently restrict the entry of data, leading to misspellings, inconsistencies etc. Providing a more versatile qualification information management system would reduce the need for manual gathering and organisation of data for reports presented to authorities on a regular basis. The system also improves data quality and contributes to fulfilling regulatory requirements of the company.

According to the company Quality Assurance (QA) director no specific GMP regulations need to be taken into account, since the signed paper documents in all instances constitute the original and the system is to be used as an administrative support system. The system should however be validated according to general GMP principles (i.e. considering consistency of information provided to authorities and having potential impacts on patient safety in mind at all times).

Glossary

Terms used in this document.

Change Control	The process of controlling and verifying all changes to a validated object, making sure that its validation status is not compromised.
Commissioning	Term used to describe a “qualification light” where a minimal amount of testing is performed.
GMP	Good Manufacturing Practise, principles and guidelines of the pharmaceutical industry focusing on patient safety
IQ	Installation Qualification, a testing procedure performed to verify that design requirements have been met and that installation has been performed correctly.
MS Excel	Microsoft Excel (full name Microsoft Office Excel) is a program that features an intuitive interface and calculation and graphing tools.
MS Sharepoint	Windows Sharepoint, is an add-on (value-add) to Windows server 2003 made available by Microsoft, which offers basic web portal and intranet functionality.
MS SQL	Microsoft Structured Query Language, a database access language for the SQL Server relational database management system.
OQ	Operational Qualification, a testing procedure performed to verify that functional requirements are met and that the object is functioning according to specification.
Material code	A product code designating a particular product provided at a particular concentration and filling size.
.NET	The Microsoft .NET Framework
Partial qualification	A sub-qualification is sometimes divided into parts to be performed separately. Can also be an addendum, re-qualification or commissioning.

PQ	Performance (or Process) Qualification, the testing procedure performed that the object performs as required.
Precondition	What is expected to be fulfilled before a use case starts.
Postcondition	The expected outcome of use case.
Primary actor	User that interacts with the system in a use case.
Qualification	The process of testing and documenting a particular object such as a computer system, a process, a method or equipment.
Re-qualification	A repetition of a qualification performed on an object at a regular interval to verify that it is still in validated status.
SOP	Standard Operating Procedure, an instruction detailing how to perform something, exists on several levels from corporate level general instructions down to department specific operating instructions for particular machinery or processes. Anything activity performed regularly that has GMP impact should be documented in a SOP.
Stakeholder	A person or organisation with an interest in the system. Stakeholders have goals that they hope to have fulfilled by the system under discussion.
Sub-qualification	Here used to designate qualifications of a specific type (e.g. IQ, OQ) that are part of a validation or another qualification.
URS	User Requirements Specification
Use case	A description of a common activity performed in the system detailing what happens step by step and who does what. Alternative flows can be defined to describe alternative paths when certain conditions vary.
Validation	The process of complete testing and documentation of a particular object that may contain several steps, qualifications (see definition above). Examples of possible parts include e.g. IQ and OQ (see definitions above).
VMP	Validation Master Plan, a document providing an overview of the validation status of equipment, processes and products of an entire company

User requirements definition

Use cases are presented in appendix 1.

1. Design requirements

#	Design requirement
1.1	It shall be possible to run the system in a Windows domain environment.
1.2	It shall be possible to run the system on Windows operating systems.
1.3	It shall be possible to use MS SQL Server 2005 for the database layer.
1.4	It shall be possible to access the system from the MS Sharepoint Server intranet.
1.5	It shall be possible to migrate and store data from the present system in the new system.
1.6	It shall be possible to configure database access information.
1.7	It shall be possible to use different database instances (e.g. training and production instance).
1.8	It shall be possible to implement single sign-on from a Windows domain account.
1.9	It shall be possible to use Windows domain groups to restrict access to the database.
1.10	A users manual and relevant system documentation shall be delivered with the system.
1.11	It should be possible to create interfaces to other information system based on relational databases.

2. Functional requirements

#	Functional requirement
2.1	It shall be possible to obtain a new, unique qualification numbers on the format X-YYYY from the system for a series X (e.g. 30, 80, 110) given by the user, where the sequence YYYY is incremented by one for each new qualification.
2.2	It shall be possible to choose if the qualification is to refer to a validation (V) or a qualification (Q) when obtaining a new number from the system.
2.3	It shall be possible to store sub-qualification numbers, along with qualification title, name of the qualification leader, project number, start date, approval date and end date in the system.
2.4	It shall be possible to store the status (e.g. NEW, APPROVED, CLOSED) of a qualification in the system.
2.5	It shall be possible to add sub-qualifications for a given qualification number.
2.6	Sub-qualifications shall be identified by the qualification number (X-YYYY) followed by V for validations and Q for qualifications, followed by a sequence.
2.7	It shall be possible to store the type of the sub-qualification (e.g. IQ, OQ).
2.8	A validation plan (main sub-qualification) shall be stored as X-YYYY-V01.

#	Functional requirement
2.9	It shall be possible to divide sub-qualification in different parts, designated as qualification number X-YYYY-[VI Q]x-Dy, where x and y are sequences for their respective categories VIQ (validation and qualification respectively) and D (Swedish “del”).
2.10	It shall be possible to add e.g. an addendum or a re-qualifications in the same manner as parts (see requirement 2.9), replacing the letter “D” with an appropriate letter (e.g. “T” for Swedish “tillägg” R for re-qualification and “C” for “commissioning”).
2.11	It shall be possible to link information about documents to a sub-qualification, including document ID, title, author, approval date, archive location and ID in the archiving system.
2.12	It shall be possible to store the type of the document (e.g. URS, Protocol, Report).
2.13	It shall be possible to store information about links to electronic documentation in the system.
2.14	It should be possible to store and access electronic documentation from within the system.
2.15	It shall not be possible to change a qualification or sub-qualification number.
2.16	It shall be possible to edit information about a qualification.
2.17	It shall be possible to edit information about documentation.
2.18	It shall not be possible to delete qualification records, document records or items being referenced by other items from the system.
2.19	It shall be possible to specify a status for qualification and document records in the system, e.g. CURRENT, OBSOLETE.
2.20	It shall be possible to copy information for a sub-qualification to create a new sub-qualification number.
2.21	It shall be possible to store and edit information about remaining activities for a sub-qualification (e.g. name of the activity, person responsible, status and date completed).
2.22	It shall be possible to store and edit product names, re-qualification interval and qualification status in the system.
2.23	It shall be possible to store and edit process steps for different products in the system.
2.24	It shall be possible to store and edit information about equipment names, re-qualification intervals and qualification status in the system.
2.25	It shall be possible to specify which product specific equipment is used for.
2.26	It shall be possible to store history for equipment use for different products with regards to the qualifications performed.
2.27	It shall be possible to store method names, re-qualification interval and qualification status in the system.
2.28	It shall be possible to link information about which products, process steps, equipment, material codes and methods are affected by a qualification.
2.29	It shall be possible to specify which change control numbers are relevant for a particular qualification.
2.30	It shall be possible to store and edit information about rooms and departments.

#	Functional requirement
2.31	It shall be possible to store and edit information about qualification series (e.g. 30 for production, 45 for laboratories etc).
2.32	It shall be possible to add free-text comments for items stored in the database.
2.33	It shall be possible to search the system for qualifications using parameters such as qualification numbers, qualification title, archive location, start, approval and end dates, product, material code, process step, equipment, method, room and department.
2.34	When searching for qualifications, it shall be possible to use wildcards (* or %).
2.35	It shall be possible to export search results in an Excel readable format.
2.36	It should be possible to invoke Excel with the exported results from within the system.
2.37	It shall be possible to add customised pre-defined reports to the system.
2.38	Wherever possible, list-of-values for users to choose from shall be used (to ensure data consistency).
2.39	It should be possible to add users to the system or to perform authentication against domain groups.
2.40	It should be possible to store user access levels within the system.
2.41	It shall be possible to choose the database instance to use at start-up.
2.42	A user should be automatically logged out of the system after 30 min of inactivity.

3. Non-functional requirements

#	Non-functional requirement
3.1	It shall be possible to have ten concurrent users in the system.
3.2	A user shall not have to wait more than 5s when storing data.
3.3	A search result shall be displayed within 2 min.
3.4	A search result should be displayed within 30s.
3.5	It shall not be possible for two users to update the same record at the same time.
3.6	Error messages shall be displayed when application and network errors occur.
3.7	On application or network failure, unsaved changes to the database shall be rolled back.
3.8	If the user closes the application without saving, any unsaved changes to the database shall be rolled back.
3.9	It shall be possible to set different access levels for different users.
3.10	Only users with administrator privileges shall be allowed to set access levels.
3.11	Users shall be able to operate the system adequately after a four-hour training course (less for read-only access).

System architecture

High-level overview of the anticipated system architecture. A relationship-entity database model can be found in appendix 2.

Fig 1. *System environment.*

Existing or planned computer systems that contain data relevant for the Qualman system.

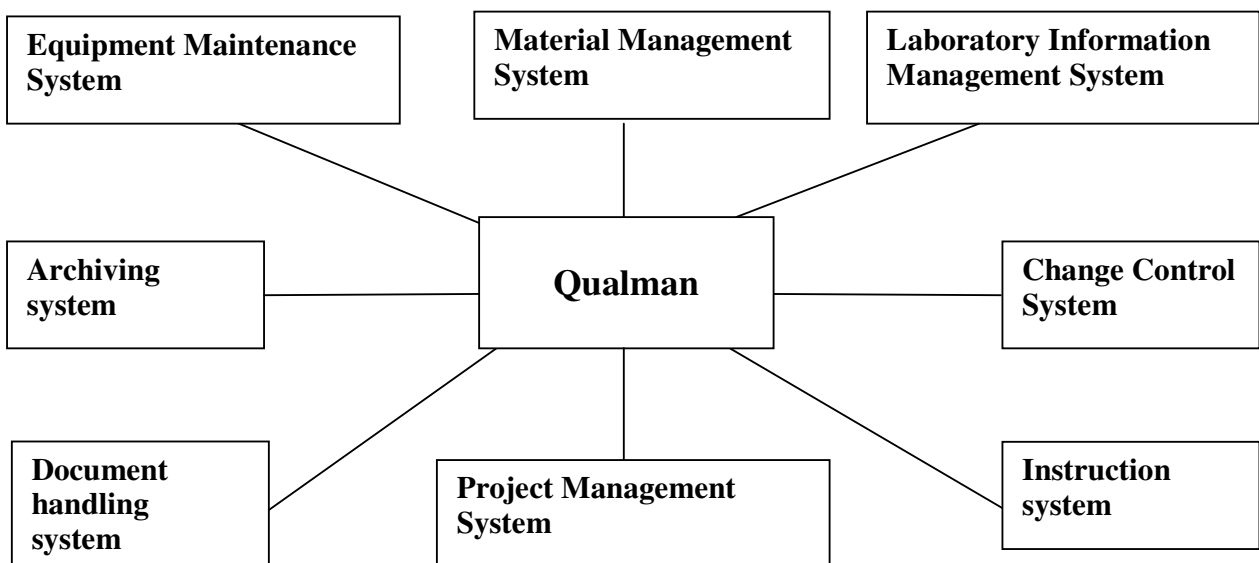
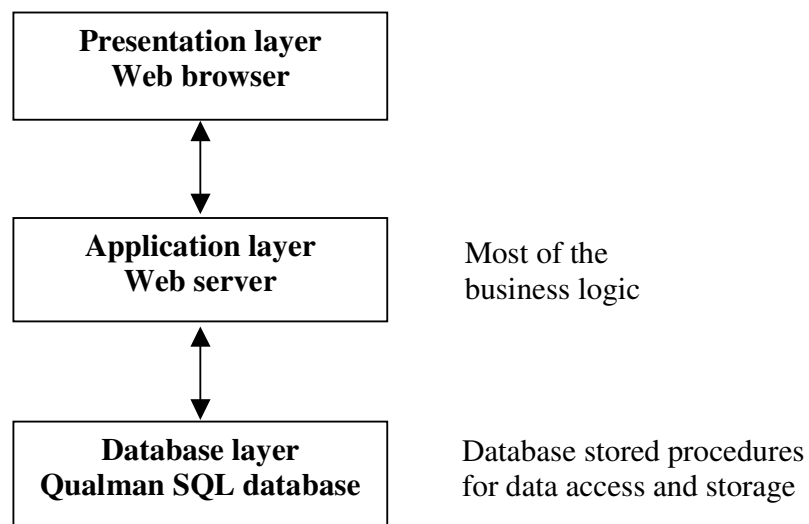


Fig 2. *3-tier client-server model*



System requirements specification

1. System design specifications

#	User Requirement
	System requirement
1.1	<p>It shall be possible to run the system in a Windows domain environment.</p> <p>The system will be developed using MS .NET 2.0 and Visual Studio 2005 and shall be compatible with a Windows environment.</p>
1.2	<p>It shall be possible to run the system on Windows operating systems.</p> <p>See comment for 1.1</p>
1.3	<p>It shall be possible to use MS SQL Server 2005 for the database layer.</p> <p>The system shall be developed for MS SQL Server 2005.</p>
1.4	<p>It shall be possible to access the system from the MS Sharepoint Server intranet.</p> <p>The system shall be developed as a .NET web application and should be possible to run from web part in MS Sharepoint.</p>
1.5	<p>It shall be possible to migrate and store data from the present system in the new system.</p> <p>Columns from tables in the existing relational database have been taken into account when designing the new data model (see appendix 2) and it shall be possible to device a migration strategy using SQL scripts although some parts may need some additional manual work.</p>
1.6	<p>It shall be possible to configure database access information.</p> <p>Database access information (such as IP address etc) shall be stored in either a configuration file or the Windows registry and will not be hard-coded in the application.</p>
1.7	<p>It shall be possible to use different database instances (e.g. training and production instance).</p> <p>There shall be a possibility to configure the system to allow choosing from a number of pre-defined database instances.</p>
1.8	<p>It shall be possible to implement single sign-on from a Windows domain account.</p> <p>The system shall verify the identity of the user against a domain account.</p>
1.9	<p>It shall be possible to use Windows domain groups to restrict access to the database.</p> <p>Domain groups shall be used to restrict access to the database.</p>
1.10	<p>A users manual and relevant system documentation shall be delivered with the system.</p> <p>A manual and system specification shall be delivered with the system.</p>
1.11	<p>It should be possible to create interfaces to other information system based on relational databases.</p> <p>The system will be implemented for SQL Server 2005 and it is possible to use .NET and SQL to export data for transfer to other systems or to import data from other relational database systems.</p>

2. System functional specifications

#	User requirement
	System requirement
2.1	It shall be possible to obtain a new, unique qualification numbers on the format X-YYYY from the system for a series X (e.g. 30, 80, 110) given by the user, where the sequence YYYY is incremented by one for each new qualification.
	Qualification numbers shall be composed of the series chosen by the user and a unique qualification number sequence and stored in the database. The sequence shall be dense.
2.2	It shall be possible to choose if the qualification is to refer to a validation (V) or a qualification (Q) when obtaining a new number from the system.
	The system shall let the user choose one of the two options validation and qualification when registering a new qualification in the system.
2.3	It shall be possible to store sub-qualification numbers, along with qualification title, name of the qualification leader, project number, start date, approval date and end date in the system.
	The system shall let the user enter the qualification information and provide the option to save the information.
2.4	It shall be possible to store the status (e.g. NEW, APPROVED, CLOSED) of a qualification in the system.
	The system shall provide a means of tracking status changes of a qualification.
2.5	It shall be possible to add sub-qualifications for a given qualification number.
	The system shall let the user choose a qualification, enter information for a sub-qualification and provide the option to save it.
2.6	Sub-qualifications shall be identified by the qualification number (X-YYYY) followed by V for validations and Q for qualifications, followed by a sequence.
	Components of the specified qualification number format shall be saved in the system.
2.7	It shall be possible to store the type of the sub-qualification (e.g. IQ, OQ).
	The system shall provide users with the possibility to choose a sub-qualification type when storing a sub-qualification in the system.
2.8	A validation plan (main sub-qualification) shall be stored as X-YYYY-V01.
	When a new validation is registered, it will be stored as X-YYYY-V01 with the title of the main sub-qualification, the validation plan.
2.9	It shall be possible to divide sub-qualification in different parts, designated as qualification number X-YYYY-[V Q]x-Dy, where x and y are sequences for their respective categories V Q (validation and qualification respectively) and D (Swedish “del”).
	Qualifications shall be stored with a series, a qualification number sequence, a qualification type (V or Q), a qualification type sequence, and, if relevant, a partial sub-qualification type (e.g. D) and a sub-qualification type sequence (se data model in appendix 2).

#	User requirement
	System requirement
2.10	It shall be possible to add e.g. an addendum or a re-qualifications in the same manner as parts (see requirement 2.9), replacing the letter “D” with and appropriate letter (e.g. “T” for Swedish “tillägg” R for requalification and “C” for “commissioning”).
	See 2.9
2.11	It shall be possible to link information about documents to a sub-qualification, including document ID, title, author, approval date, archive location and ID in the archiving system.
	The system shall provide an interface for linking document information to sub-qualifications.
2.12	It shall be possible to store the type of the document (e.g. URS, Protocol, Report).
	The system shall provide users with the possibility to choose a document type when storing information about a document in the system.
2.13	It shall be possible to store information about links to electronic documentation in the system.
	The system shall provide the possibility to store links to electronic documentation.
2.14	It should be possible to store and access electronic documentation from within the system.
	The system should provide possibilities to store a document from within the system and to trigger the appropriate application for a chosen document to show its contents.
2.15	It shall not be possible to change a qualification or sub-qualification number.
	Stored qualification and sub-qualification numbers shall not be possible to change.
2.16	It shall be possible to edit information about a qualification.
	The system shall provide an interface to edit qualification information excluding qualification number.
2.17	It shall be possible to edit information about documentation.
	The system shall provide an interface to edit document information.
2.18	It shall not be possible to delete qualification records, document records or items being referenced by other items from the system.
	The system shall not allow users to delete neither qualification nor document records from the system. It shall also not be possible to delete records being referenced by other items.
2.19	It shall be possible to specify a status for qualification and document records in the system, e.g. CURRENT, OBSOLETE.
	The system shall provide a means to store a status for a qualifications and documents.
2.20	It shall be possible to copy information for a sub-qualification to create a new sub-qualification number.
	The system shall provide a means to copy a sub-qualification to a user-specified new sub-qualification number within the same qualification.

#	User requirement
	System requirement
2.21	It shall be possible to store and edit information about remaining activities for a sub-qualification (e.g. name of the activity, person responsible, status and date completed).
	The system shall provide an interface for entering and editing information about remaining activities.
2.22	It shall be possible to store and edit product names, re-qualification interval and qualification status in the system.
	The system shall provide an interface for storing and editing product information.
2.23	It shall be possible to store and edit process steps for different products in the system.
	The system shall provide the possibility to store and edit process step information for a product.
2.24	It shall be possible to store and edit information about equipment names, re-qualification intervals and qualification status in the system.
	The system shall provide an interface for storing and editing equipment information.
2.25	It shall be possible to specify which product specific equipment is used for.
	The system shall provide the possibility to store and edit information about which product(s) specific equipment is used for.
2.26	It shall be possible to store history for equipment use for different products with regards to the qualifications performed.
	The system shall provide an equipment version history with regards to uses for different products.
2.27	It shall be possible to store method names, re-qualification interval and qualification status in the system.
	The system shall provide an interface for storing and editing method information.
2.28	It shall be possible to link information about which products, process steps, equipment, material codes and methods are affected by a qualification.
	The system shall provide possibilities to link qualifications to products or material codes, process steps, equipment and methods.
2.29	It shall be possible to specify which change control numbers are relevant for a particular qualification.
	The system shall provide possibilities to store information about change control numbers relevant for a particular qualification.
2.30	It shall be possible to store and edit information about rooms and departments.
	The system shall provide an interface for storing and editing room and department information.

#	User requirement
	System requirement
2.31	It shall be possible to store and edit information about qualification series (e.g. 30 for production, 45 for laboratories etc).
	The system shall provide an interface for storing and editing qualification series information.
2.32	It shall be possible to add free-text comments for items stored in the database.
	There shall be possibilities to add free-text comments for all the main entities in the system.
2.33	It shall be possible to search the system for qualifications using parameters such as qualification numbers, qualification title, archive location, start, approval and end dates, product, material code, process step, equipment, method, room and department.
	The system shall provide extensive possibilities to search for qualification information in the system.
2.34	When searching for qualifications, it shall be possible to use wildcards (* or %).
	The system shall provide possibilities to use wildcards for searches.
2.35	It shall be possible to export search results in an Excel readable format.
	The system shall provide a means to export search results in a MS Excel readable format.
2.36	It should be possible to invoke Excel with the exported results from within the system.
	The system should be able to invoke MS Excel to display search results.
2.37	It shall be possible to add customised pre-defined reports to the system.
	Using a third-party report tool, e.g. Crystal reports, could provide report functionality to the system.
2.38	Wherever possible, list-of-values for users to choose from shall be used (to ensure data consistency).
	The system shall present the user with list-of-values to choose from for all items that have pre-defined possible values stored in the system.
2.39	It should be possible to add users to the system or to perform authentication against domain groups.
	The system shall use either comparison of user Windows domain identity to user access lists in the database or authentication based on domain groups.
2.40	It should be possible to store user access levels within the system.
	The system will provide means of storing access levels for system users unless this can be handled entirely using domain groups.
2.41	It shall be possible to choose the database instance to use at start-up.
	The system shall provide the possibility to choose the database instance to use at start-up.
2.42	A user should be automatically logged out of the system after 30 min of inactivity.
	The system should provide a mechanism for automatically logging out users that have been inactive for a specified period of time.

3. System non-functional specifications

#	User requirement
	System requirement
3.1	It shall be possible to have ten concurrent users in the system.
	The system shall allow for ten users concurrently being logged into the application.
3.2	A user shall not have to wait more than 5s when storing data.
	There shall be no more than a 5s delay before control of the interface is returned to the user.
3.3	A search result shall be displayed within 2 min.
	SQL queries for searches shall be optimised to run in less than 2 minutes under normal network traffic and server load conditions, provided that the capacity of the server and network is adequate.
3.4	A search result should be displayed within 30s.
	See requirement 3.3. It should be possible to have the search run in less time although the amount of data as well as server and network capacity have an impact on the response times.
3.5	It shall not be possible for two users to update the same record at the same time.
	Database transaction handling shall be used for all operations where there is a risk of two users concurrently updating the same record in the database.
3.6	Error messages shall be displayed when application and network errors occur.
	Error handling shall be used whenever possible in the application and a list of errors and error messages shall be provided as part of the system documentation.
3.7	On application or network failure, unsaved changes to the database shall be rolled back.
	Database standard rollback functionality rolls back all session information that has not been committed to the database. Transaction handling will be used.
3.8	If the user closes the application without saving, any unsaved changes to the database shall be rolled back.
	See 3.7.
3.9	It shall be possible to set different access levels for different users.
	Access levels admin, create, change and read shall be implemented.
3.10	Only users with administrator privileges shall be allowed to set access levels.
	Administrator access level shall be required to set access levels for other users.
3.11	Users shall be able to operate the system adequately after a four-hour training course (less for read-only access).
	The system shall be transparent and intuitive enough that it in combination with the system documentation will make it possible for users to operate it after a four-hour training course.

System evolution

Fundamental assumptions on which the system is based

- Qualman will only be required to operate in a MS Windows environment with the .Net 2.0 framework installed. The only database it will be required to interface with is MS SQL Server 2005.
- The users will have documented education of the system before they use it.
- Qualman will only be used on via the company Intranet.
- The .Net 2.0 framework will be installed on the clients.

Anticipated future changes to the system

A clustered server environment using VM-ware may be used in the future. Hardware changes are however not expected to have an effect on the system.

User requirements for the system may change in the future. Needs for storage of additional information may arise. The system may also become subject to integration with other systems, either by extension of the system or through interfaces transferring information to or from Qualman. Possible candidate systems for integration and interfaces are the equipment management, material management, archiving, document handling, instructions, project planning, and change control systems (see Fig. 1).

Customised report templates will most likely need to be created for a number of reports in the system.

List of use cases

Use cases are found in appendix 1.

- UC1 Add a new qualification number
- UC2 Add a sub-qualification to a qualification
- UC3 Add a partial qualification to a qualification number
- UC4 Add or edit qualification information
- UC5 Add a new qualification document
- UC6 Close a sub-qualification
- UC7 Edit remaining activities for a sub-qualification
- UC8 Edit List-of-Values information, e.g. qualification series
- UC9 Edit equipment information
- UC10 Edit material code information
- UC11 Search for qualifications and export data to Excel
- UC12 Add a new user

Index of diagrams

Fig. 1 *System environment.*

Existing or planned computer systems that contain data relevant for the Qualman system.

Fig. 2 *3-tier client-server model.*

Use Cases

Use Case UC1: Add a new qualification number

Primary Actor: System administrator (or person with rights to create new qualification numbers)

Stakeholders and Interests:

- Qualification group leader: Wants to have a new qualification number.
- System administrator: Wants to take out a unique qualification number from the system and to store relevant qualification information
- Company: Wants to identify each qualification with a unique number to provide traceability.

Precondition: User with create access rights is authenticated and logged in.

Postcondition: A new qualification number, the type of qualification (validation or qualification), the first sub-qualification sequence number, and the title and qualification leader have been stored.

Main Success Scenario:

1. The qualification group leader provides the Qualman system administrator with the title of the validation or qualification plan and specifies the qualification type and what qualification series is to be used.
2. The system administrator opens the new qualification number interface and enters the name of the qualification leader and the qualification title
3. The system administrator chooses the qualification series (e.g. 30, 45, 80) from a list-of-values.
4. The system administrator chooses the qualification type (Validation or Qualification) from a list-of-values.
5. The system administrator chooses to save the entered information.
6. The system creates a new qualification number for the given series (e.g. 30-1122) and stores it.
7. The system stores the qualification type and adds a sub-qualification V01 if it is a validation and Q01 if it is a qualification.
8. The system stores the title, the qualification leader, the user ID of the user saving the information and the current date and time.
9. The system presents the new qualification number (e.g. 30-1122-V01 or 30-1122-Q01) to the system administrator and confirms that the number has been saved.

Alternative Flows:

- 3a. The system administrator chooses to cancel the operation.
 1. The system does not save anything.

Use Cases

Use Case UC2: Add a sub-qualification to a qualification

Primary Actor: System administrator (or person with rights to create new qualification numbers)

Stakeholders and Interests:

- Qualification group leader: Wants to have a new sub-qualification number.
- System administrator: Wants to obtain a unique sub-qualification number from the system and to store relevant qualification information
- Company: Wants to identify each sub-qualification with a unique number to provide traceability.

Precondition: User with create access rights is authenticated and logged in.

Postcondition: A unique sub-qualification number, the title and the qualification leader have been stored in the system.

Main Success Scenario:

1. The qualification group leader informs the Qualman system administrator to which main qualification number the sub-qualification should be added, what the title is and which type of sub-qualification is to be added.
2. The system administrator opens the interface to add sub-qualifications and searches for the main qualification number (on the format XX-YYYY, e.g. 30-1122).
3. The system shows a list of the sub-qualifications already stored for the given main qualification number.
4. The system administrator selects the sub-qualification type (e.g. IQ, OQ) from a list-of-values.
5. The system presents the system administrator with the next sub-qualification number available (e.g. 30-1122-V02).
6. The system administrator enters the sub-qualification title and qualification leader.
7. The system administrator chooses to save the sub-qualification.
8. The system stores the title, the qualification leader, the user ID of the user saving the information and the current date and time.
9. The system confirms that the sub-qualification number has been saved

Alternative Flows:

- 3a. The qualification number is not found.
 1. The system displays an error message.
- 5a. The sequence is not the one wanted.
 1. The system administrator changes the sequence of the sub-qualification (to e.g. V10 instead).
- 7a. The system administrator chooses to cancel the operation.
 1. The system does not save anything.

Use Cases

Use Case UC3: Add a partial qualification to a qualification number

Primary Actor: System administrator (or person with rights to create new qualification numbers)

Stakeholders and Interests:

- Qualification group leader: Wants to have a new sub-qualification number for a partial qualification.
- System administrator: Wants to obtain a unique sub-qualification number for a partial qualification from the system and to store relevant qualification information.
- Company: Wants to identify each sub-qualification with a unique number to provide traceability.

Precondition: User with create access rights is authenticated and logged in.

Postcondition: A unique sub-qualification number for a partial qualification, the title of the partial qualification and the qualification leader have been stored in the system.

Main Success Scenario:

1. The qualification group leader informs the Qualman system administrator to which main qualification number the part of a sub-qualification should be added, what the title is and which type of part of sub-qualification is to be added.
2. The system administrator opens the interface to add sub-qualifications and searches for the main qualification number (on the format XX-YYYY, e.g. 30-1122).
3. The system shows a list of the sub-qualifications already stored for the given main qualification number.
4. The system administrator selects the sub-qualification to add the partial qualification to.
5. The system administrator chooses the type of partial qualification (e.g. re-qualification, addendum, partial, “commissioning” (see glossary)).
6. The system presents the system administrator with the next partial sub-qualification number available (e.g. 30-1122-V02-D01 or 30-1122-V02-R01 depending on the partial qualification type).
7. The system administrator enters the sub-qualification title and qualification leader.
8. The system administrator chooses to save the sub-qualification.
9. The system stores the title, the qualification leader, the user ID of the user saving the information and the current date and time.
10. The system confirms that the sub-qualification number has been saved.

Alternative Flows:

- 3a. The qualification number is not found.
 1. The system displays an error message.
- 6a. The sequence is not the one wanted.
 1. The system administrator changes the sequence of the partial sub-qualification (to e.g. D02 instead).
- 8a. The system administrator chooses to cancel the operation.
 1. The system does not save anything.

Use Cases

Use Case UC4: Add or edit qualification information.

Primary Actor: System administrator (or other user with change privileges).

Stakeholders and Interests:

- Qualification group leader: Wants qualification information to be changed.
- System administrator: Wants to update the qualification information in the system.
- Company: Wants to have the correct qualification information recorded in the system.

Precondition: Qualification information stored is incorrect.

User with change access rights is authenticated and logged in

Postcondition: The qualification information is updated.

Main Success Scenario :

1. The qualification group leader provides the system administrator with the qualification information to be stored.
2. The system administrator searches for the qualification in question in the system.
3. The system presents a list of the sub-qualifications for the given qualification.
4. The system administrator chooses the sub-qualification number in question from the list.
5. System displays the stored information for the selected qualification.
6. System administrator edits the qualification information (e.g. title, qualification leader).
7. System administrator chooses combinations of process steps and products affected by the qualification from a list-of-values.
8. System administrator chooses combinations of material codes and products affected by the qualification from a list-of-values.
9. System administrator chooses combinations of methods and departments affected by the qualification from a list-of-values.
10. System administrator chooses the equipment version (connected to stored information about products it is being used for) affected by the qualification from a list-of-values.
11. The system administrator chooses to save the entered information.
12. The system stores the information that has been changed or entered and displays a confirmation message.

Alternative Flows:

- 4a. The qualification number is not found in the system.
 1. The system returns an error message.
- 5a. The qualification information displayed is incorrect.
 1. The system administrator corrects it and saves the corrected information.
- 7a. Process step information is not relevant
 1. The step is omitted.
- 8a. Material code information is not relevant
 1. The step is omitted.
- 9a. Method information is not relevant
 1. The step is omitted.
- 10a. Equipment information is not relevant
 1. The step is omitted.
- 11a. The system administrator chooses to cancel the operation.
 1. The system does not save anything.

Use Cases

Use Case UC5: Add a new qualification document.**Primary Actor:** System administrator (or other person with change access rights)**Stakeholders and Interests:**

- Qualification group leader: Wants a new qualification document to be recorded.
- System administrator: Wants to update the system with a new qualification document.
- Company: Wants all documents produced during qualifications to be recorded in the system.

Precondition: Qualification document contains the qualification number.

System administrator is authenticated and logged in.

Postcondition: System is updated with information about a new document.**Main Success Scenario:**

1. The qualification group leader gives the qualification document to the system administrator.
2. The system administrator searches for the qualification number in the system.
3. The system returns a list of sub-qualifications for the given qualification number.
4. The system administrator chooses the correct sub-qualification number from the list.
5. The system returns the title and the qualification group leader of the qualification and the qualification start date.
6. The system administrator enters the document title, author, approval date, physical archive location and electronic storage path.
7. The system administrator chooses the document type from a list-of-values.
8. The system administrator chooses to save the document.
9. The system generates document ID, stores the given information, the user ID and the current date and time, sets the document entry status to CURRENT, and presents a confirmation that the document information has been stored.

Alternative Flow:

- 3a. The qualification number is not found in the system.
 1. The system returns an error message.
- 8a. The system administrator chooses to cancel the operation.
 1. The system does not save anything.

Use Cases

Use Case UC6: Close a sub-qualification.

Primary Actor: System administrator.

Stakeholders and Interests:

- Qualification group leader: Wants sub-qualification to be completed and closed.
- System administrator: Wants to update the system with sub-qualification information and close the qualification.
- Company: Wants complete qualification information and qualification status to be recorded in the system.

Precondition: System administrator is authenticated and logged in. UC4, Add or edit qualification information has been followed as far as step 5.

Postcondition: Sub-qualification has been closed. User is returned to UC4 with the sub-qualification information displayed having been updated.

Main Success Scenario:

1. System administrator selects to close the sub-qualification.
2. System administrator fills in the remaining activities, responsible person and the planned date of completion.
3. System administrator fills in any general information regarding the qualification in a free-text space for comments.
4. System administrator chooses to close qualification.
5. The system stores the information entered, sets the end date to the current date and time, changes the status of the qualification to closed and displays a confirmation message.
6. The system returns the user to the entry point of the use case and updates the displayed sub-qualification information.

Alternative Flows:

- 2a. No remaining activities exist,
 1. The step is omitted.
- 3a. No extra information needs to be recorded
 1. The step is omitted.
- 4a. The system administrator chooses to cancel the operation.
 1. The system does not save anything.

Use Cases

Use Case UC7: Edit remaining activities for a sub-qualification.

Primary Actor: System administrator.

Stakeholders and Interests:

- Qualification group leader: Wants to add remaining activities for the sub-qualification.
- System administrator: Wants to update the system with remaining activities information.
- Company: Wants all qualification information to be recorded in the system.

Precondition: System administrator is authenticated and logged in. UC4, Add or edit qualification information has been followed as far as step 5.

Postcondition: Remaining activities information for a sub-qualification has been updated. User is returned to UC4 with the sub-qualification information displayed having been updated.

Main Success Scenario:

1. The system administrator selects to edit remaining activities.
2. The system administrator enters or changes the activity information.
3. The statuses of the activities that have been finished are set to closed.
4. The system administrator selects save the entered information.
5. The system saves the changes and displays a confirmation message.
6. The system returns the user to the entry point of the use case and updates the displayed sub-qualification information.

Alternative Flows:

- 3a. No activities are finished,
 1. The step is omitted.
- 4a. The system administrator chooses to cancel the operation.
 1. The system does not save anything.

Use Case UC8: Edit List-of-Values information, e.g. qualification series.

(Similar use cases are relevant also for e.g. qualification types, sub-qualification types, partial sub-qualification types, document types, equipment types, products, departments, rooms and methods)

Primary Actor: System administrator

Stakeholders and Interests:

- System administrator: Wants to maintain a list of possible qualification series.
- Company: Wants to identify different qualification series.

Precondition: A user with administrator access rights is authenticated and logged on.

Postcondition: Information of available qualification series numbers has been updated.

Main Success Scenario:

1. The system administrator selects to edit series.
2. The system displays a list of the currently available qualification series.
3. The system administrator makes additions to the list.
4. The system administrator chooses to save the changes.
5. The system stores the edited information, the user ID and current date and time, and displays a confirmation message.

Alternative Flow:

- 4a. The system administrator chooses to cancel the operation.
 1. The system does not save anything.

Use Cases

Use Case UC9: Edit equipment information.

Primary Actor: System administrator.

Stakeholders and Interests:

- System administrator: Wants to store information about equipment and its use for different products in the system
- Company: Wants all equipment information relating to qualifications to be stored and available for reports.

Precondition: System administrator is authenticated and logged in.

Postcondition: The equipment information has been updated.

Main Success Scenario:

1. The system administrator searches for the equipment to edit using equipment type or name.
2. The system displays a list of equipment matching the search criteria.
3. The system administrator chooses the equipment to edit.
4. The system displays the information on the equipment.
5. The system administrator chooses to create a new version of the equipment.
6. The system displays the information that is carried over between versions and waits for input for the new data.
7. The system administrator chooses which products it is being used for from a list-of-values.
8. The system administrator chooses the equipment type, room and department from list-of-values.
9. System administrator chooses to save.
10. The system creates a new version of the equipment, stores the information entered, user ID and the current date and time and displays a confirmation message.

Alternative Flows:

- 2a. No previous equipment of the given name and type exists.
 1. The system displays a message.
 2. The system administrator chooses the option to add new equipment.
- 9a. The system administrator chooses to cancel the operation.
 1. The system does not save anything.

Use Cases

Use Case UC10: Edit material code information.

(Similar use cases are relevant also for e.g. editing process step and instruction information)

Primary Actor: System administrator.

Stakeholders and Interests:

- System administrator: Wants to store information about material codes for different products in the system
- Company: Wants all material code and product information relating to qualifications to be stored and available for reports.

Precondition: System administrator is authenticated and logged in.

Postcondition: The material code information has been updated.

Main Success Scenario:

1. The system administrator chooses to edit material codes.
2. The system administrator searches for a material code to edit.
3. The system displays information for the material code.
4. The system administrator edits the information.
5. The system administrator selects to save.
6. The system updates the material code information, saves the user ID, the current date and time and displays a confirmation message.

Alternative Flows:

- 2a. The system administrator chooses to add new material code
 1. The system administrator enters the name of the new material code.
 2. The system administrator chooses the relevant product and department from list-of-values.
 3. The system administrator chooses to save the information.
 4. The system adds a new material code, saves the entered information, the user ID, the current date and time and displays a confirmation message.
- 5a. The system administrator chooses to cancel the operation.
 1. The system does not save anything.

Use Cases

Use Case UC11: Search for qualifications and export data to Excel.

Primary Actor: System user.

Stakeholders and Interests:

- System user: Wants to be able to use the system for searching of the needed information about qualification.
- Company: Wants to be able to retrieve information to present to authorities from the system.

Precondition: The user is authenticated and has read access to the system.

Postcondition: The user gets the needed information.

Main Success Scenario:

1. The user fills in information for the needed search criteria.
2. The user chooses to start the search.
3. The system returns a list of all the relevant qualifications according to search criteria.
4. The user chooses to export the results to Excel.
5. The system exports the result set and invokes Excel.
6. The user chooses to save the Excel file.
7. System user repeats steps 1-6 if he/she wants to search for more qualifications.
8. System user logs out.

Use Case UC12: Add a new user.

(Depending on the access solution implemented, this use case may need to be modified)

Primary Actor: System administrator.

Stakeholders and Interests:

- User: Wants to be able to get the needed access to the system to fulfil her/his tasks.
- System administrator: Wants to give users the correct access level needed to perform their tasks.
- IT department: Wants account management to be efficient. Wants user to have access to the system though their domain account and to restrict access based on domain groups.
- Company: Wants security requirements for the system to be fulfilled and wants employees to have the appropriate access to be able to do their job.

Precondition: An access request form has been filled out by the user and signed both by the user and system administrator.

The system administrator is authenticated and logged in.

Postcondition: The user has been granted access to the system at the appropriate level. The system has stored the user information. Needed software has been installed on the user's computer.

Main Success Scenario:

1. The system administrator enters personal information, domain account information and access level for the new user.
2. The system administrator chooses to save the new user.
3. The system stores the information, along with the user ID of the system administrator and the current date and time, and displays a confirmation message.
4. The system administrator informs the IT department of the new user.
5. The IT department adds the user to the relevant domain group and installs any needed software on the user's computer.

Alternative Flow:

- 2a. The system administrator chooses to cancel the operation
 1. The system does not save any information.

Qualman data model

