**Necessary Regulatory/Compliance System Requirements**

* QMS user groups setup that allows full authority, document editing and read only. Read only can open, add comments but cannot make the document “live” without supervisor/manager approval and the final approval of the QA team. See below for further details.
* Employees in departments can enter requests but cannot approve or delete requests.
* Managers group can enter or approve a request but cannot delete requests.
* Members of the Administrators group can edit, enter, approve and delete requests.
* No printing function available to anybody except administrators of the system. All documents will be printed off and placed into a file for reference. See below.
* You are able to maintain one controlled copy of each document, meaning there are no hard copies to continually update.  Whether you have one office or a hundred, allowing authorised individuals instant access to critical documents decreases red tape and confusion.
* The database will have a functional audit trail. With version control and users who have accessed and added comments/changes. And even when the document was created. Example below



* The audit templates can be signed off with electronic signatures.
* Department folders to have abbreviations allocated to them to use for version control etc.

**Further Document Security Requirements**

* All documents are created as MS Word documents or PDF. Once created, the documents are standard Word or PDF documents and are maintained or amended using edit function in our own document management system.
* Only approved documentation is displayed in one location
* Evidence of compliance is available at your finger tips
* Auditors love the Document module as they can view document control at one location, all online with full version control.
* Control of documentation is quick and easy to maintain
* Once a document is open by another user, it should be read only by any other user.

**System requirements**:

* **Requirements and Protocols** 
  + User, Functional, and Design specifications
  + Installation, Operational, and Performance Qualifications
  + User, Software Acceptance Tests
* **Risk Assessment –** Evaluation of the risk of each system requirement and generate risk reports.
* **Validation Summary Reports –** Automatically create a reports that include executed Test Cases, Deviations, and Resolutions.
* **Data Migration –** Documentation for data migration protocols.
* **Change Control –** Documents reporting on all changes.

**Comprehensive Automation of Validation Processes, Including:**

* Validation Plans
* User Requirements Specifications, Functional Specifications and Design Specifications
* Requirements Traceability Matrix
* Test Protocols
* Summary Reports
* Deviation Summary Reports

**Wish list – Action at a later date:**

* Documents / templates to be fully functional within the software. Using drop down boxes and open text boxes, with print function of the final document. Removing the need to open a word document and having to manually insert all information into the document.
* Full email function, notifying user groups / individuals or all staff that changes have been made to documents, processes or anything related to the QMS.
* An add on to the email function would be whenever a staff member has updated or added comments to a document, automated emails will be sent to advise administrators that this has happened.
* Printing of any document should be watermarked and also the user wishing to print the document has to acknowledge a prompt in the regards to the document no longer being controlled.
* Calendar function to add audit dates and times, reminders of upcoming audits, inc. compliance audit for external auditor. This will also come with an email function where you could email a department about an upcoming audit with a acknowledge email returned to document audit details.
* If training becomes an option, you could setup training / testing days, with an online training available, also with reminders set for retraining. Such as first aid.
* Software version control. Every time QMS is updated, the version gets updated as well. To show external auditors that we are constantly moving forward. Maybe even a documented log of these updates/changes.
* Adding in purchase order templates. Once completed, they are sent via email directly to the accounts department.
* The use can be increased to cover the safety side of the company, safety audits, legislation etc.
* If non-conformance has been issued, this can be logged, with actions required to correct with review and “deadline” set in the calendar, with reminders.
* Auto archiving of documents. Once a document has been updated, as soon as the new document is saved, the previous version is archived.
* The QMS would have a dashboard function where there would be tabs on the screen where the user can navigate to anywhere they need to go. Policy/procedure/templates/ quality manual/legislation/user manuals-guides etc.
* Management review meetings,