Confluence is a knowledge and document management platform that can manage files i.e., attachments. By utilising the different ways Confluence can manage attachments it can be used as a knowledge and document management platform. Attachments are files that are included with a page. Confluence lets you control who can add new attachments and who can open attachments on the space level. Once you attach a file, you can provide a link to it from any Confluence page or display a list of attachments for that page. If you attach a file with the same name as an existing attachment, Confluence will create a new version of the existing attachment.

The wiki allows all documents to be stored in a place where everyone can view and review them.

A. ISO Requirements

<table>
<thead>
<tr>
<th>No.</th>
<th>Requirement</th>
<th>Description</th>
<th>Satisfied by</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Quality management system</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.2</td>
<td>Documentation requirements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.2.1</td>
<td>General</td>
<td>The QMS documentation must include:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Organization’s Quality Policy and Quality Objective</td>
<td>Confluence</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Quality Manual</td>
<td>Comalatech Tools</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Documented Procedures and records required by ISO 9001 QMS</td>
<td>Customer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Documents and records, determined by the organization to ensure the</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>effective planning, operation and control of its processes.</td>
<td></td>
</tr>
</tbody>
</table>

Confluence allows users to store documentation in pages and attachments.

Confluence tracks the history of changes to each page, keeping all versions.

The organization must provide the proper documentation.

Confluence unambiguously identify and stores changes, which can be recovered, compared or rolled back in any moment.

Confluence wiki capabilities promote collaboration and peer-review processes, together with automatic notifications of changes ensure prompt content review.

Comalatech Document Management provide capabilities to ensure reviewing and approval of documents.

Comalatech does not claim compliance or certification of any of our tools, as it is not possible for any vendor to offer a compliant system. In addition to taking advantage of technical elements, compliant systems must also implement the necessary procedural and administrative controls.

Need help setting up Confluence and Comala Document Management for controlled documents? Contact Us.
| 4.2.4 Control of records | Records provide the evidence of conformity with ISO 9001 requirements, so the process must be controlled. The organization must establish a documented procedure to define the controls for the identification, storage, protection, retrieval, retention and disposition of records. | Confluence ensures only authenticated user have access to system content, the definition of users and groups ensures the access to content based on those groups. In addition, records are safe because all versions are saved automatically. | Comala Document Management maintains control of the approved version of each document, and can control which version of the document is available to each user, based on their role. Alternatively, Comala Publishing provides a solution to separate approved from draft content in distinct, separate spaces. | The customer must control the access to the physical storage devices. |

| 5 Management responsibility | 5.1 Management commitment | Top management must show evidence of its commitment to this process by: | Confluence can notify with emails to whoever needs to know the changes, communicating immediately to the proper roles. | Comala Document Management can set tasks to be fulfil by specific roles. | The company’s top management staff must ensure the fulfiment of the quality in objectives and polices. |

| 5.3 Quality policy | Top management is responsible to establish a quality policy, which must: | Confluence allows the communication of the documents to the members of the organization, allowing its revision and continuous improvement. | Comala Document Management provides capabilities to set tasks and the approval of documents. | The company’s top management staff must create the quality policy. |

| 5.4.2 Quality management system planning | Top management must ensure: | Confluence keeps the integrity of the data. Links and page titles are automatically updated when there are changes. | Top management must review the QMS planning. |

| 5.5.1 Responsibility and authority | Top management must ensure that responsibilities and authorities are defined and communicated to the organization e.g., job description and organizational charts | Confluence provides a people directory and each person has a personal profile. This profile shows the position, department and personal data. Besides that, each user can maintain a personal space. Thus, all responsibilities can be communicated. | Top management must ensure that staff have an updated job description and can provide an organizational chart. |

| 5.5.2 Management representative | Top management must appoint a member of the organization to be “Management representative”, who has to: | Comala Share It provides a unique public link that can be shared outside Confluence to communicate with external parties. | Top management must choose a capable management representative. |

| 5.5.3 Internal communication | Top management must ensure that the communication processes are established, also regarding the effectiveness of the QMS. E.g., meeting reports are an evidence. | Confluence is a social tool used for internal communication, allowing content creation, comments and likes on the content, personal blogs, etc. | | |
### 5.6 Management review

#### 5.6.1 General
Top management must review the QMS, at planned intervals, to ensure:
1. its continuing suitability,
2. its adequacy and effectiveness,
3. opportunities for improvement.
Records of this review must be kept (4.2.4).

Confluence simplifies content reviewing by the use of recent changes, page history, subscription to content changes in your favourite spaces or network.

Comala Document Management allows the description of a workflow to review and approve documentation.

Top management must ensure the revision of the QMS.

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#### 5.6.2 Review input
This review must include:
1. results of audits,
2. customer feedback,
3. process performance and product conformity,
4. status of preventive and corrective actions,
5. follow-up actions from previous management reviews,
6. changes that could affect the QMS, and
7. recommendations for improvement.

Confluence provides different kind of pages to publish the inputs: meeting notes with control of attendants, how-to articles, product requirements, reports, pages, retrospectives, decisions, task lists, links, etc.

Comala Canvas provides different kind of pages to publish the inputs: task canvas or strategy canvas.

---

#### 5.6.3 Review output
The output must include decisions and actions related to
1. improvement of the effectiveness of the QMS and its processes,
2. improvement of product related customer requirements, and
3. resource needs.

Confluence provides different kind of pages to publish the outputs: meeting notes with control of attendants, how-to articles, product requirements, decisions, task lists, links, etc.

Comala Canvas provides different kind of pages to publish the outputs: task canvas or strategy canvas.

Alternatively, Comala Publishing provides a solution to separate approved from draft content in distinct, separate spaces.

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### 8 Measurement, analysis and improvement

#### 8.2 Monitoring and measurement

#### 8.2.2 Internal audit
The organization must carry out, at planned intervals, internal audits to determine if the QMS:
1. conforms to the ISO 9001 and the QMS requirements,
2. is effectively implemented and maintained.

Considering:
1. the status and importance of the processes,
2. the areas to be audited,
3. the results of previous audits,
4. the results from external auditors

Internal auditors must be trained and competent and cannot audit their own work.

Confluence allow users to create visual roadmaps for planning audits, add-ons exist to create forms, everything can be printed and signed in case it needs to be send physically.

Comala Document Management can set tasks to specific users and ensure that auditors cannot audit themselves.

Comala Share It allow users to externally send pages once the internal audit is finished.

The organization must ensure the training of the internal auditors.

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#### 8.3 Control of nonconforming product
The organization must ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

The organization must establish a documented procedure to define the controls and responsibilities and authorities for dealing with nonconforming products, which includes:
1. eliminating the product,
2. authorizing its use, release or acceptance by the customer,
3. excluding its original use,
4. taking appropriate actions to the effects when the product is already delivered.

Confluence provides a product requirement, decision and meeting notes kind of pages to keep track of the customer product requirements, meetings and decisions derived from them. Thus, nonconforming products can be identified.

Comala Document Management allow users to set a workflow to control the state of the different pages involved on the documented procedure.

The organization must ensure the proper workflow setting and roles involved on the documented procedure.
### 8.5.2 Corrective action

<table>
<thead>
<tr>
<th>The organization must establish a procedure to define:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. reviewing nonconformities, including customer complaints,</td>
</tr>
<tr>
<td>2. determining the causes,</td>
</tr>
<tr>
<td>3. evaluating the need to ensure that nonconformities don't occur,</td>
</tr>
<tr>
<td>4. determining and implementing the actions needed,</td>
</tr>
<tr>
<td>5. records of the results,</td>
</tr>
<tr>
<td>6. reviewing the effectiveness of the corrective actions.</td>
</tr>
</tbody>
</table>

Confluence tasks can be used to indicate actions and areas to be improved by team members. Confluence capabilities could be improved if used together with Atlassian JIRA for doing so.

Comala Document Management consolidates document creation and modifications with the approval and signing audit records. A time-stamped log of workflow operation actions is also maintained, and associated with each document.

The organization must ensure the proper workflow setting and roles involved on the documented procedure.

### 8.5.3 Preventive action

<table>
<thead>
<tr>
<th>The organization must establish a procedure for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. determining potential nonconformities and their causes,</td>
</tr>
<tr>
<td>2. evaluating the need to prevent nonconformities,</td>
</tr>
<tr>
<td>3. determining and implementing the actions needed,</td>
</tr>
<tr>
<td>4. records of the results,</td>
</tr>
<tr>
<td>5. reviewing the effectiveness of the preventive actions.</td>
</tr>
</tbody>
</table>

Confluence tasks can be used to indicate actions and areas to be improved by team members. Confluence capabilities could be improved if used together with Atlassian JIRA for doing so.

Comala Document Management consolidates document creation and modifications with the approval and signing audit records. A time-stamped log of workflow operation actions is also maintained, and associated with each document.

The organization must ensure the proper workflow setting and roles involved on the documented procedure.

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Note: this list is based on Comala Document Management ISO 9001 Section 4 (Quality Management System) Compliance Statement, "Achieving ISO certification", Iso requirements and "Using Document Control Software to Meet ISO Document Control Requirements".

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**Implementation of ISO**


Following text is extracted from Comala Document Management ISO 9001 Section 4 (Quality Management System) Compliance Statement.

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**Additional QAD Document Rqmts**

To have both review and approval cycles. The document owner or editor determines the review cycle and participants. The system automatically routes the document to the participants via email notification. Review and approval signatures to be executed.

Process Documents (SOPs) must be approved by a minimum of two people, the Process Owner and Quality Assurance. In the case of multiple process owners, each will need to approve.

The document owner or editor determines the approval cycle and participants. The system automatically routes the document to the participants via email notification. Quality Assurance is the last approver.

The document owner or editor enters the Purpose from the attached Word file and the Summary of Changes.

The document owner or editor enters all documents referenced within the attached document into the References section.

When the document owner or editor creates a new document, fills in the required fields and saves the document, the system automatically assigns a unique document ID. The document is created with the revision number -0. Document information must be entered into the document attachment.

Document owners or editors set the review interval to 24 months for Process documents (SOPs). FDA Compliance requires Process documents be reviewed every 24 months. If the process is valid and no changes are required, it can be renewed. A renewal comment will be required. FDA

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**Required**

The system automatically assigns the next revision number to updated or revised documents. The document owner or editor determines the review participants. This can be the past reviewers or a new set of reviewers. Once submitted for review, the system automatically routes the document to the participants via email notification.

To preclude the use of invalid and/or obsolete documents, verify that the on-line controlled master list of current revisions for all process documentations is easily available and documents are uniquely numbered using an increased revision number.

To provide access to all obsolete and withdrawn documents. This includes any withdrawn revisions of unpublished documents.