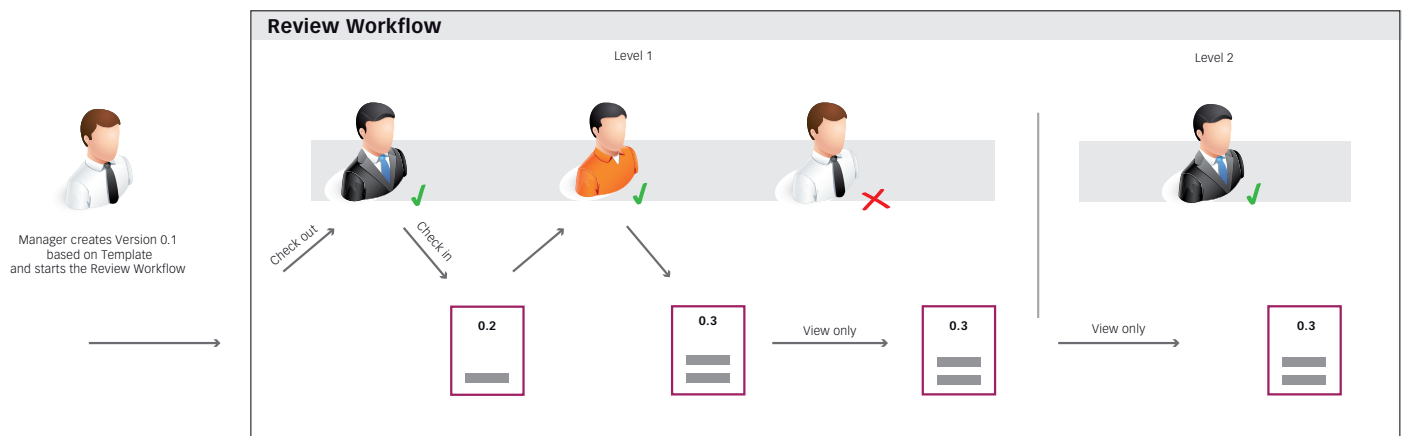## Regulated Documents / Workflow

Supports users to manage the entire lifecycle of regulated documents within Carizma-QM itself.

Creation

The author defines key information e.g. document type (SOP, work instruction, form, checklist, etc.), title of document, process owner (department), groups of users to whom the document is applicable, review cycle.
Users are defined in due time by e-mail when a document needs to be reviewed.
Carizma creates the skeleton document.

Preparation

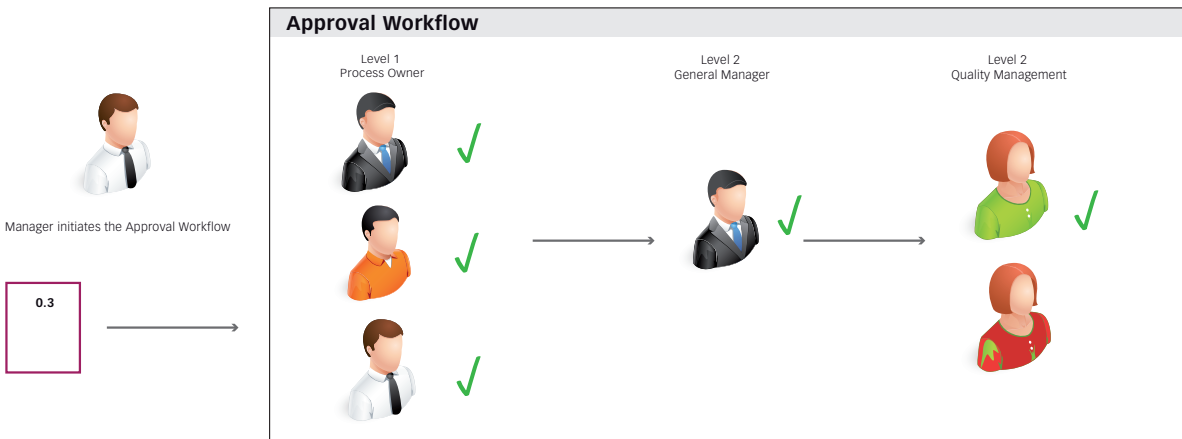The author opens the document in MS-Word and prepares the document by adding the subject matter.

Review

The author has the option to initiate a review workflow to request additional experts to add content or to review the draft version. Each time the document is modified, it is stored as a new version after it has been checked in.

Regulated Documents / Workflow

Approval

As soon as the author is content with the document s/he initiates an approval workflow – e-mails are sent to the approvers (defined in the workflow) with the request to approve the document. Approvers have the option to reject or to accept a document. As soon as all requested approvers have approved the document the status is set to "approved" and the document is converted to PDF format with the electronic signature(s) added. The author can then define the date on which the document becomes effective.

Approval Workflow

Level 1
Process Owner

Level 2
General Manager

Level 2
Quality Management

Manager initiates the Approval Workflow

0.3

Training

Users defined in the "applicable to" groups are requested by e-mail to read the approved document and confirm (electronic signature) that they will comply with the requirements and obligations contained in the document (Read & understood). The training status for each document and user is tracked and is readily available.

Training («Read and understood» Workflow)

1.0

√ «Read and understood»

√ «Read and understood»
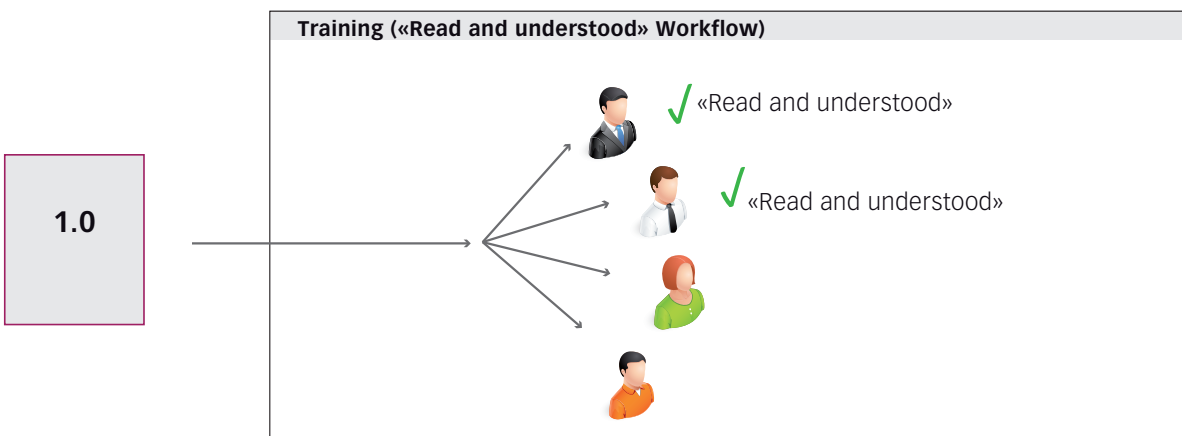
Users who are added to an "applicable to" group at a later point in time, e.g. new employees, are automatically informed by e-mail about the documents they have to read.

Dissemination

The effective version is made available automatically to all users via the companies intranet side. Numerous filters for searching documents as well as full text search are available.