# Purpose of documents

The TQM documents on this web platform are to be used per the specifications of the subcontractor’s order to ensure that the project is handled in accordance with ProLeiT’s quality standards.

The TQM documents are to be observed and completed in the respective project phases depending on the scope of delivery.  
  
The use of the TQM documents is described below.  
  
ProLeiT ensures that the latest TQM documents are always stored. Changes can be found in the document “**revision history document subcontractors.xlsx**”.  
The actual TQM documents must be used.

# Use of documents

**Documents with information**

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| **Name of document** | **Project phase** | **Purpose** |
| QMA\_A\_0310\_Programming\_standards\_plant\_software\_EN | Realisation | Guidelines for developing software in a project |
| QMA\_C\_1019\_Start\_up\_security\_policy | Commissioning | Safety instructions to be considered at commissioning, to avoid the risk of personal and material damage |

**List of documents to be submitted**

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| --- | --- | --- | --- |
| **Name of document** | | **Project phase** | **Use/content** |
| QMA\_C\_1005\_Minutes\_of\_a\_meeting\_EN | | Multiple phases | Template for recording meeting results |
| QMA\_C\_1014\_Technical\_Design\_EN | | Clarification | Create functional specifications with the customer.  Check functional specifications for clarity, consistency, feasibility and completeness  assess and implement any changes to the contract.  The functional specifications have to be verified and released by the project manager before delivery to the customer |
| QMA\_C\_1015\_general\_concept\_plant\_software | | Clarification | A general description on how the automation should work; this solution should develop with the collaboration of all project participants. No customer involvement required. |
| QMA\_C\_1017\_fine\_concept\_plant\_software\_EN | | Clarification | A fine concept is a document containing the detailed description of how to implement the customer’s requirements and thus serves as a “programming template”. |
| QMA\_C\_1018\_FDS\_Acceptance\_EN | | Multiple phases | Document for release the function descriptions of the plant by the customer |
| QMA\_C\_1023\_Check\_list\_project\_clarification\_phase\_EN | Clarification | | Checklist requesting customer specifications. |
| QMA\_C\_1024\_checklist\_program\_test\_sequence\_EN | Realisation | | Requirements for testing the sequences |
| QMA\_C\_1025\_Check\_list\_module\_test\_EN | Realisation | | Requirements for testing individual software modules (a module is a completed program unit with defined input and output values) |
| QMA\_C\_1026\_Check\_list\_integration\_test\_EN | Realisation | | Requirements for testing over several modules, to verify if the expected results occur with the configured input parameters. |
| QMA\_C\_1029\_test\_protocol\_GAMP\_PLS\_EN | Realisation | | Test template for PLS projects in the pharmaceutical field (according to GAMP guidelines)  This template can be used for the module test as well as the integration test. |
| QMA\_C\_1038\_Testprotokoll\_Allgemein\_DE | Realisation | | General test template for MES and PLS projects. This template can be used for the module test as well as the integration test. |
| QMA\_C\_1003\_Minutes\_of\_the\_FAT\_EN | Commissioning | | This document outlines the details agreed upon in the FAT protocol signed by the customer. This also specifies if defects are a work in progress or should be eliminated prior to the cutsomer’s release of delivery. Depending on the agreement it is possible to bill invoices at this point. |
| QMA\_B\_0503\_Minutes\_of\_the\_training\_EN | Commissioning | | If the customer training occurs during commissioning, the training content and participants trained are to documented. This document serves as proof that the training has been performed. |
| QMA\_C\_0904\_Change\_request\_form\_EN | Commissioning | | This document is used to specify additional expenses incurred due to customer change requests. |
| QMA\_C\_1209\_Acceptance\_procedure\_protocol\_EN | Commissioning | | This document must be used when the project has an engineering budget over 25.000 Euro. It contains additional service information provided by ProLeiT GmbH  The warranty must be specified here  By signing this document the customer legally confirms that our services are fulfilled and that the customer accepts the liability of risk and property. A partial acceptance may also be possible. In this case, it is necessary to document which services (e.g. hardware installation) have been processed. This agreement must be referred to explicitly and preferably attached. Any outstanding faults should be added to the deficiency list. |
| QMA\_C\_1210\_Before\_returning\_from\_plant\_EN | Commissioning | | This checklist serves as an aid for the person responsible for commissioning before leaving the plant. The checklist does not need to be signed by the customer. |
| QMA\_C\_1211\_Report\_completion\_commissioning\_EN | Commissioning | | Certifies the handover of the plant to the customer and the end of commissioning  Should be used, if the acceptance is not signed by the customer. |
| QMA\_C\_1212\_Timesheet\_acceptance\_certificate\_EN | Commissioning | | This document is used for projects with an engineering cost less than 25.000 €. Very important: the commissioning hours must be signed by the customer before leaving their site. The work carried out during commissioning must be specified in this document. |
| QMA\_D\_1505\_Customer\_questionnaire\_EN | Commissioning | | This document will be delivered to the customer for all projects with an engineering cost over 25.000 €. The delivery must be logged in the QMA\_C\_1209\_Acceptance\_procedure\_protocol\_EN document. |