# Takeda – On the Job Training Development – Work Instruction

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| PURPOSE AND SCOPE |
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| This Work Instruction describes the steps for developing On-the-Job Training (OJT) materials at MA Bio Ops. |

| 1.    ANALYSIS HAND OFF | |
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| **Basic Checklist** | 1.1.    OJTQ (On-the-Job Training Qualification) should be aligned for issuance with the parent SOP. |
| | 1.2.    Determine if the OJTQ is cross-functional in scope. Check Training Needs Assessment, if applicable. |
| **Needs Assessment Steps for New OJTQ** | 1.3.    Document owner of the Parent SOP determines a need for a new OJTQ to assess performance (i.e., new process, CAPA, CC, legacy training guide or ILT Open, etc.). |
| | 1.4.    Document owner reviews related documents per SOP-053185: EDMS Lifecycle, and should reach out to Learning Solutions Team (LST) to evaluate for LMS assignments. |
| | 1.5.    LST obtains an L&D resource for review/approval of the OJTQ. |
| | 1.6.    Document owner reviews existing SOPs, TGMs, KCs, PPTs, etc. associated with the creation of the OJTQ (contact Ma Bio Ops L&D to obtain legacy training materials). |
| | 1.7.    Document Owner identifies SMEs and applicable Stakeholders for the OJTQ content. |
| **Prepare OJTQ Draft** | 1.8.    Document owner/OJTQ author drafts the content using the current OJTQ template as an outline. See **SOP-052458:** MABioOps On-the-Job Training Qualification Process. This begins with the purpose: (Example Purpose: Qualify the trainee to perform associated tasks.). |
| | 1.9.    Document owner/OJTQ author drafts the description for the OJTQ in the field provided. |
| | 1.10.  Document owner develops a list of the needed tasks to perform the operation for the OJTQ. |

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| **Task** | 1.11. Document owner drafts answers to several questions to identify the steps that make up a task in the final assessment:<br><br>Recommended questions:<br>• How often is the task performed? Is it a repetitive (routine task) or an emergency task that is rarely performed?<br>• How critical is the task - what are the consequences of failing to do the task correctly?<br>• How difficult/complex is the task?<br>• How many steps are required to master the task?<br>• Can subtasks be grouped together to form a competency?<br>• What knowledge/skills should be a prerequisite before starting the task?<br>• What behaviors must be in place to ensure the integrity of the activity?<br>• What is the desired training outcome?<br>• What must the learner be able to do - under what performance standards/conditions (criteria)? |
| **Writing Objectives** | 1.12. After documenting the task list, Document Owner uses the identified critical steps to write the Final Assessment criteria (performance qualification steps).<br><br>1.13. Document owner writes objectives using an action verb (reference Bloom's Taxonomy) when developing your objectives. Consult L&D (assigned ID) with questions or requests for feedback.<br><br>1.14. Limit objectives to approximately 4-5 depending on the complexity of the operation. |
| **Scope Provided Section** | 1.15. Document owner lists the TGM number, in the Scope Provided section, for the OJTQ being developed. This number is obtained after this document is initiated in Veeva and is used in the course code identification.<br><br>1.16. Consult with L&D (assigned ID) if you believe your OJTQ is cross functional and needs more than 1 course code (different audiences or different QTs). |
| **Prerequisites** | 1.17. Document owner or SME identifies and documents in this section SOP's, OJTQ's, or Roles required for completion prior to completing the OJTQ. |

| 2. INSTRUCTIONAL DESIGN CHECK? |
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| **OJTQ Objectives, Topics and Activities** | 2.1. ID reviews and determines correlation between the objectives and the final assessment tasks, and provides feedback as needed.<br><br>2.2. ID confirms Training Function and Owner approval before starting development.<br><br>2.3. Determine overview and background formatting:<br>    2.3.1. Print-based<br>    2.3.2. eLearning / WBT (include link in OJTQ) |

| | 3. DEVELOPMENT |
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| **Associated OJTQ Collateral** | 3.1. L&D resource (ID or LID) establishes the OJTQ development timelines. Reference the OJTQ Development Timeline per the TNA WI. The Timeline will be attached to the Project Management Tool.<br><br>3.2. Per the approved course design document / draft OJTQ, establish OJTQ collateral:<br><br>   3.2.1. Overview and Background – Document owner writes how the process works including illustrations or pictures to highlight the critical steps.<br><br>   3.2.2. If your overview/background is more than 2 pages, reach out to the LST member for recommendations regarding eLearning format for Overview and Background.<br><br>   3.2.3. The next field is where trainee confirms they understand the overview/background. |
| **Draft the OJTQ Template** | 3.3. Doc Owner obtains the current OJTQ Template from **SOP-052458:** MABioOps On-the-Job Training Qualification Process.<br><br>   3.3.1. Draft the Purpose based on review of the related documents and stakeholder discussion.<br><br>   3.3.2. Draft the Scope/Credit To Be Provided using the current/future state mapping if needed.<br><br>   3.3.3. In the prerequisite section of the OJTQ template:<br><br>      3.3.3.1. For any WBT/OB (Overview and Background) Content, deployed by the LMS, list the associated TGM as a prerequisite to the OJTQ.<br><br>      3.3.3.2. Reference Current/Future state mapping documents if applicable for SOPs and related documents.<br><br>   3.3.4. Draft the Performance Qualification Requirements. These are the Learning/Performance Objectives.<br><br>   3.3.5. Create Overview and Background content.<br><br>   3.3.6. Determine the number of Practices and Observations required.<br><br>3.4. Document owner may request review or feedback during the development of their OJTQ from the assigned ID.<br><br>3.5. The Document Owner creates the Final Assessment, referencing the objectives to ensure correlation between the tasks and the final assessment criteria.<br><br>   3.5.1. Consider the difficulty, criticality and frequency of the tasks included in the final assessment. Reference SOP-052458: MABioOps On-the-Job Training Qualification Process. |

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| **Initiate 1st Draft Review** | 3.6. In Veeva, the Document Owner submits the **1st Draft** for Review and Revision: |
| |     3.6.1. *Example OJT Qualification (OJTQ) Template* of **SOP-052458:** MABioOps On-the-Job Training Qualification Process. |
| |     3.6.2. Initiate Veeva review cycle per **QM-003032:** *Veeva Vault Quality Docs User Manual* with stakeholders. |
| |     3.6.3. Reviewers for the OJTQ should include the SME, Document Owner. ID and an L&D member. |
| **Initiate 2nd Draft Review** | 3.7. In Veeva, the Document Owner submits the **2nd Draft** for Review and Revisions: |
| |     3.7.1. If first draft is acceptable, with no major revisions needed, proceed to final approval. |
| | 3.8. Initiate Veeva review cycle per **QM-003032:** *Veeva Vault Quality Docs User Manual* with stakeholders as needed. |
| |     3.8.1. Repeat review cycle as needed. |
| **Complete Final Draft for Approval** | 3.9. In Veeva, the Document Owner submits the **Final Draft** for Veeva Approval per **QM-003032:** *Veeva Vault Quality Docs User Manual.* |
| | 3.10. Approvers for the OJTQ should include the Document Owner, L&D member, and Quality. |
| | 3.11. Additional reviewers (i.e., QA) may be required for CAPA's, deviations, and change control. |

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| **4.  OJTQ REVISIONS** | |
| **Preparing and Reviewing OJTQ Edits** | 4.1. For revisions: |
| |     4.1.1. Document Owner downloads the Word version source file from Veeva, for the OJTQ being revised, and provides redline edits based on SOP revisions. |
| |     4.1.2. The Document Owner initiates the Veeva review cycle and includes the L&D resource (LID or ID) to ensure OJTQ is instructionally sound. |
| |         4.1.2.1. The Document Owner continues with Veeva review and approval cycles to complete the OJTQ revision. |
| |     4.1.3. Ensure metadata is updated to reflect whether training is needed or not - equivalent to the current version. |
| | 4.2. Document owner confirms current QT status in the LMS to add or remove QTs as needed. |
| |     4.2.1. If changes to QTs, supply Form 053540: Qualified Trainer Authorization Form. |
| | 4.3. Document Owner submits Form 061266: Learner Change Request Form to waive SME or new QTs as needed. |

| **5. OJTQ IMPLEMENTATION** |
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| **Logistics, LMS Upload and Deployment** | 5.1. Complete Veeva Approval cycle: <br><br> 5.1.1. Confirm "Training Window": duration in days from the "Issued Not Yet Effective" Date to the "Effective" Date as indicated on Veeva page. OJTQ Author coordinates with parent SOP document owner to align effective dates (if applicable). <br><br> 5.1.2. When all Approvals are in, ID/Veeva Coordinator must set the Effective Date (minimum of 16 days). The date that the ID/Veeva Coordinator takes the action to set the Effective Date is the Issue Date ("Issued Not Yet Effective"). The Effective Date is the date set in Veeva based on the "Training Window" as described above. <br><br> 5.1.3. Issue document in Veeva. <br><br> 5.1.4. LMS upload per LSO processing. <br><br> 5.1.5. LSO Sends email communication to document owner to confirm any associated forms have been processed (see suggested steps from the eLearning WI). |

| **6. COURSE EVALUATION** |
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| **Description: Evaluation** | ID and LID use the (OJTQ Evaluation Form - TBD) to check with the QT and/or recent trainees to determine if OJTQ is meeting business needs. (i.e., sufficient O/B content, appropriate objectives and final assessment tasks and final assessment criteria, gaps, any improvements/clarification). <br><br> • Collect and review OJT surveys on a routine basis. (per evaluation strategy) <br> • Major content/delivery gaps/issues should be addressed immediately. <br> • Minor issues should be worked into the OJTQ revision cycle. |
| **Initiate Evaluation** | 6.1. ID and LID distribute OJTQ Evaluation Form to participants/QTs (hard copy or electronic) if needed. <br><br> 6.1.1. Solicit feedback and comments if OJTQ has potential issues/concerns. <br><br> 6.2. Collect and review completed evaluations forms for trends indicating revisions are needed. |
| **Follow Up and Revise as Needed** | 6.3. ID and LID send communication to stakeholders to confirm changes are needed based on evaluation trends. <br><br> 6.4. ID and LID update/revise OJTQ materials as needed per evaluation feedback and stakeholder confirmation. |
| **Revise Content** | 6.5. Initiate OJTQ development and associated review cycles as needed per **Section 4** above. |

| TERMS AND DEFINITIONS |
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**OJTQ First Draft:** A near-complete build of the OJTQ, although some minor content may be missing.

**OJTQ Second Draft:** Fully developed version of the OJTQ with all associated changes from the first draft review.

**OJTQ Final:** The completed course that incorporates all issue resolutions required per the second draft review.

**Final Assessment:** The training activity in which a QT evaluates the trainee's ability to perform the listed OJT tasks independently against predefine criterion.

| REFERENCED DOCUMENTS |
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**SOP-052458: MABioOps On-the-Job Training Qualification Process**

**QM-003032: Veeva Vault Quality Docs User Manual**

| ATTACHMENTS (OPTIONAL SECTION) |
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**FORM**     **OJTQ Evaluation Form**

| REVISION HISTORY SUMMARY | |
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| **Revision** | **Summary of Changes** |
| 01 | **New document.** |