Quality Control Document:

Laboratory Competencies

# Purpose

When considering whether an individual is competent to perform, or competent to train others, in relation to the use of laboratory equipment and assays, it is important to define and assess competency. This ensures that individuals have the correct competencies to analyse and/or evaluate human biomaterial samples for clinical trials. The purpose of this document is to provide competent-to-train and competent-to-perform Laboratory Competencies form templates. The use of these templates is optional.

The Laboratory Competencies form templates can be used to record the outcome of individual competency assessments that relate to specific, required competencies for a named piece of equipment or assay. These form templates may be used by the person who has been named on the trial’s/study’s laboratory roles and duties log as being responsible for defining laboratory competencies. See the Laboratory Roles and Duties SOP (UoB-CRL-QCD-002) for a laboratory roles and duties log template.

This document is expected to be used for clinical trials of investigational medicinal products (CTIMPs). For the purpose of best practice, these templates may also be used for non-CTIMP trials and studies.

# Instructions

1. Remove this first instruction page.
2. Update header to include the trial/study ID.
3. Update the footer, retaining the document reference information relating to this quality control document (QCD).
4. Update the Equipment/Assay Title (in both ‘Competent to Train’ and ‘Competent to Perform’ laboratory competency forms).
5. Record competency criteria (including both competent to train and competent to perform) for each assay/equipment using the table in the Laboratory Competencies form. Remove/add rows in the table as required. Consider the following when defining competency criteria:

* Is previous experience required? For example, consider the number of years performing an assay, using a piece of equipment, or number of publications
* How many observations / repeats are required?
* What is the acceptance criteria? For example, the minimum number of monocytes isolated form a whole blood sample.

1. Ensure the Laboratory Competencies forms are made available to the team to ensure that trainers and trainees are aware of their expected training.
2. File each Laboratory Competencies form with the competency criteria completed under the ‘Laboratory Competencies’ section in the laboratory master file. See the quality control document (QCD) Setting Up a Laboratory Master File (UoB-CRL-QCD-001).
3. Trainees will complete a Laboratory Competencies form for each equipment/assay they are trained to be competent/a trainer in. The trainer will sign to confirm the trainee’s competency and the trainee will keep these originals with their training documentation, e.g. in a personal development folder.
4. Instruct the trainee to log completion of their Laboratory Competencies forms for each competency on their training log.

# Related documents

* UoB-CRL-QCD-001 Setting Up a Laboratory Master File
* UoB-CRL-QCD-002 Laboratory Roles and Duties
* UoB-CRL-SOP-001 Laboratory Set-up and Management
* UoB-CRL-SOP-002 Laboratory Facilities
* UoB-CRL-SOP-003 Sample Management
* UoB-CRL-SOP-004 Laboratory Analysis
* UoB-CRL-SOP-005 Reportable Issues
* UoB-TRN-SOP-001 Training

UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT (<mailto:crct@contacts.bham.ac.uk>) and/or from the RGT ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).

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| --- | --- | --- | --- |
| Name: |  | Job Title: |  |

# Competent to Train statement - <Equipment / Assay Title>

To be competent to train individuals on this assay / use of this equipment the following criteria must be met:

|  |  |  |
| --- | --- | --- |
| Criteria | Date Completed | Assessed By |
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## Approval:

By signing this record, I confirm that this person has met the above competence criteria and is competent to train individuals on the use of this assay/equipment:

|  |  |
| --- | --- |
| Name: |  |
| Function: |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Signature: |  | Date: |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Name: |  | Job Title: |  |

# Competent to Perform statement - <Equipment / Assay Title>

To be competent to perform this assay / use this equipment the following criteria must be met:

|  |  |  |
| --- | --- | --- |
| Criteria | Date Completed | Assessed By |
|  |  |  |
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## Approval:

By signing this record, I confirm that the person above has met the above competence criteria and is competent to perform/use this assay/equipment:

|  |  |
| --- | --- |
| Name: |  |
| Function: |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Signature: |  | Date: |  |