

UC Davis – Western Region IR-4 Field Office
4218 Meyer Hall UC Davis, Davis, CA 95616

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| Title: Handling of Field Data Notebooks | |

PURPOSE: To define requirements for all personnel when handling field raw data in the form of field data books sent in from the Western Region Field Research Directors to the Western Region IR-4 Field Office.

SCOPE: Applies to all GLP study Field Data Books (FDB) for the residue trials conducted in the Western Region IR-4 Program.

PROCEDURES:

- 1.0** Field Data Books (the original raw data documenting a residue field trial) will be sent into the Western Region Field Office upon completion of the field trial. Documented arrival of field samples at the appropriate analytical laboratory will be considered the completion of the field portion of a residue trial.
- 2.0** Upon arrival at the Western Region Field Office each notebook will be signed in as per the chain of custody page by the Regional Field Coordinator or designee.
- 3.0** Upon arrival at the Western Region Field Office each original notebook will be scanned, saved to the server, appropriately labeled, logged into the WR Online Database as “received” and shelved in the Western Region Field Office.
- 4.0** Notebooks will be assigned for a quality control (QC) review by the Regional Field Coordinator or designee. The QC reviewer(s) may be the Regional Field Coordinator or appropriately trained IR-4 staff or qualified external consultants. The RFC will maintain scanned CVs of all QC reviewers on the field server. Updated CVs will be requested, scanned and saved approximately every 2 years. If the notebooks are leaving the Western Region Field office for QC review they will be signed out via the chain of custody form in the notebook and sent via FEDEX or other trackable mail to the QC reviewer. If the books are remaining in the Western Region Field Office for review or being hand delivered to the QC reviewer, the QC reviewer will be documented in the online database.
- 5.0** The role of the QC reviewer is to ensure that the documentation is complete in the notebook as to study conduct and GLP compliance. The reviewer will use a standard checklist as provided by the Regional Field Coordinator or designee as a guide to conducting the review. All application calculations will be checked and verified using a standard EXCEL spreadsheet provided by the Western Region Field Office. Alternatively long hand methods of calculation or customized EXCEL spreadsheets may be used when appropriate for studies not suited to the standard EXCEL spreadsheets.

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- 6.0** The reviewer will send an email to the appropriate Field Research Director (FRD) or their designee to request any clarifications or corrections they deem necessary to complete the documentation for the trial represented by the notebook. The FRD or their designee will provide corrections or changes via email in response to the QC reviewer's questions and suggested edits. The QC reviewer is permitted to make changes to the field data book with the approval of the FRD or their designee. The clarifications, approved edits or changes are made to the notebook and the documentation correspondence will be printed and provided in Part 3 Notes and Communications Log Section of the Field Data Book.
- 7.0** Electronic scans of changed or added notebook pages are provided to the FRD via email so the FRD has a record of changed pages in the original notebook that will be sent on to QA for the Field Raw Data Audit.
- 8.0** When the field data book QC review is complete, the notebook is returned to the Western Region Field Office. A final complete scan is made of the notebook, QC checklist, and application verifications. The final scan is stored on the Western Region server at least until the notebook is archived at IR-4 Headquarters. The file name is updated in the online database for posting to the IR-4 Works website: <https://ir4works.org/frd/field-data-notebook/> FRDs are to use this scanned copy when responding to any additional changes requested in subsequent QA audits.
- 8.1** If the notebook is from a confidential study, it will not be posted on the IR-4 Works website but will instead be made available to the FRD upon request.
- 9.0** The notebook is then signed out of the Western Region field office via the chain of custody form on the notebook. The Field office staff then sends the reviewed notebook on to the assigned QA unit for audit. The WR online database is updated indicating the date the FDB is sent on to QA via FEDEX or an appropriate trackable mail system. If the notebook remains in the Western Region for QA audit, it is hand delivered to the Western Region Quality Assurance Unit.