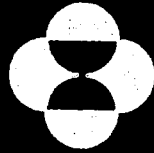


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269-180



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LABORATORY NOTEBOOK

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NOTEBOOK PROCEDURE*

This notebook is the property of Merck and Co., Inc. and will contain confidential, proprietary, and trade secret information. The notebook records are important legal documents essential for obtaining patent protection on inventions and federal approval for our product applications. It is assigned to you, remains your responsibility while in your possession, and should be retained on Merck premises except when required for conducting business or experiments on non-Merck premises or when transporting it between Merck buildings. Should you transfer to another Department or Division, this notebook and all ancillary data related to the experiments in it must be returned to the closest Research Information-MRL (RI) site for disaster protection; if required again, it can be charged out to anyone with legitimate need. All incomplete notebooks will periodically be protected by microfilming or optical scanning, according to a schedule maintained by RI. This notebook will serve as a primary source of experimental results. However, the use of a notebook is not restricted to experimental work, but includes all matters for which a readily identifiable, properly witnessed, and dated record may be useful (government regulations, litigation, patent purposes, *etc.*). To assure that this notebook is a useful document, follow these procedures.

- 1) Enter directly in this notebook all your objectives, ideas, experimental plans, experimental data, observations, calculations, *etc.* Do not put data on loose sheets and then transcribe them to this book.
- 2) Make all entries in dark, indelible ink, preferably black, using a pen which creates an impression (*e.g.*, ballpoint).
- 3) All entries should be from a single author; entries by others should be clearly identified.
- 4) Erasures, whiting out, writing over, taping over, or pasting over are not permitted. Make corrections by lining out with a single line (do not obliterate entry), initialing, dating, and explaining.
- 5) All entries must be made in the notebook at the time of the experiment. The date of each recorded experiment must be entered in the notebook using a non-ambiguous Merck Standard format (*e.g.*, 15 Dec. 1997). Each day's entries must be signed and dated by the user immediately below the last entry. The signature should include first name, initial, and surname (or what is commonly used by the investigator on legal documents); when multiple entries are made on different dates, each entry should be dated and signed.
- 6) Write on both left- and right-handed pages of the book. Include all observations, notes, references, quotations, discussions, calculations, sketches, *etc.*
- 7) In recording experiments, clearly identify by appropriate reference: starting materials, end products, protocols, controls, results, conclusion, cross-references, *etc.*
- 8) The record must be continuous so that no suspicion of interpolation, falsification, or amendment can be aroused. Accordingly, all entries must be made consecutively with no blank pages. Vacant spaces on a page should be marked out with a diagonal line or an "X", dated, and initialed. All entries related to previously numbered and paginated experiments must be designated by a reference in the margin.
- 9) Each page must be countersigned by someone not likely to be a co-inventor but who understands the significance of the recorded experiments. Countersigning should be done within a reasonable time after the experiment. **NOTE:** If the Standard Operating Procedure (SOP) for the experiment specifies the frequency of countersignature, countersignature should follow that SOP consistently (*e.g.*, if the SOP states that countersignature will occur at the completion of each experiment, then it should occur one time at the end of each experiment; if the SOP states weekly countersignature will occur, then countersignature should be accomplished weekly).
- 10) Any essential ancillary records such as photographs, computer printouts, spectra, graphs, memos, technical reports, *etc.* which may substantiate or validate your notebook should be referenced to the notebook number and page and be kept together as a reference to that notebook. A reference to the ancillary data should also be entered on the notebook page.
- 11) Complete a Table of Contents or index to enable ready access in the future by yourself or others. Pages are provided for this purpose in the front of the book. Index pages for unbound notebooks may be obtained from RI.
- 12) The records must be maintained in compliance with your written departmental procedure on keeping laboratory notebooks.

*Complete instructions are in MRL Policies, Procedures and Charters Manual, Policy 23, "Writing and Maintaining Preclinical Laboratory Records", available from Research Information, MRL.

May, 1998

NOTEBOOK NUMBER: 26180

ASSIGNED TO:

Print Rebecca Leigh Shultz

Signature Rebecca Leigh Shultz

DATE: 14 Mar 2002



PAGES 1 TO 152

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LABORATORY NOTEBOOK

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