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b UNIVERSITÄT BERN

LABORATORY NOTEBOOK

Notebook No.:

Assigned to:_____

Date:

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Laboratory Notebook Guidelines – Contract					
Created:	Approved:	Date:	Revision:	Issue:	$\boldsymbol{\mathcal{U}}$
QM scientists, University of Berne	Faculty, University of Berne	02.04.08	0	11.07	
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Instructions for scientific documentations issued by the University of Berne

Introduction

Using a laboratory notebook to record ideas, inventions, experimentation records, observations and all work details is a vital part of any laboratory process. Careful attention to how the laboratory notebook is kept can have a positive impact on the patent outcome of a pending discovery or invention. A patent/manuscript is granted to the inventor/investigator who was the first/principal investigator to conceive the invention/to perform the investigation. Therefore, the laboratory notebook is evidence for proving inventorship /investigation of the project. It establishes a permanent record detailing what was done during the course of a project and what inventions/investigations were made and when. The laboratory notebook is a legal document recording the chronological history of all activities.

Responsibilities of the scientist

It is the responsibility of the scientist to keep up to date with the most recent process instructions (laboratory notebook guidelines, labeling guidelines for generated material), checklists of the institution and backups.

Regulation of the properties of scientific documentations

Laboratory notebooks belong to the University of Berne and must remain in the laboratory when the investigating scientist leaves the institution. The scientist may make copies of any laboratory notebooks used to take with him/her. Similarly, after expiration of the working contract, all electronic data must be moved to a location to which only the administrator of the institution has access. The documents will be stored for at least 3 years after publication of the data.

Read and understood:

Date

Name and signature of scientist

Date

Name and signature of supervisor

Approved by the Dean of the Medical Faculty of the University of Berne:

Date

Name and signature of Dean

P. E_{ll}i

March 20, 2014

Prof. Dr. med. Peter Eggli



Process specification

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Standard operating procedure - recording scientific investigations

Lab book guidelines

These minimal requirements are based upon negotiations of QSE and QMS responsible scientists of the University of Berne.

What to record in a notebook¹

ALL RECORDS HAVE TO BE WRITTEN IN ENGLISH

- All entries should be made consecutively. Pages must not be removed or torn out of the notebook. Pages must not be skipped or left with large empty areas. When necessary, unused page sections can be marked of with an "X".
- 3. **Entries** should be made **on the same day** as the event. If this is not possible, the information must be entered with the indication of when the actual work was done.
- 4. Each notebook page must be signed.
- 5. Records should be **permanent, complete and continuous**. Use permanent, waterproof ink for handwritten notes.
- 6. Entries have to be written legibly.
- 7. Entries must not be erased or blotted out. If errors need to be corrected, a single line must be drawn through the incorrect information and the corrected information added to the text. All crossed out items have to be signed and dated. Reasons for the correction have to be noted.
- 8. Each experiment or procedure has to be assigned a **title and a consecutive number starting with the investigator initials**. Below the title, a brief comment should explain why the particular procedure was performed. What is the expected **outcome**?

All generated material which has to be stored and/or used for further experiments must be labeled with the number of the project, the investigators unique initials and the entire date. This label has to be cross-referenced in the laboratory notebook.

- 9. Records must be sufficiently detailed and clear to allow someone "skilled in the art" to recreate the work and to conduct additional work without the direct assistance of the original investigator. All details of a project should be recorded: This includes raw data and final results of experiments, protocols and experimental design, calculations on which the results are based, details of equipment and material used, and a key to any abbreviations used.
- 10. **Raw data** from recording instruments, drawings, photographs, charts, computer printouts, etc. must be included. These items have to be **permanently attached** to a notebook page and

¹ Exceptions must be explicitly approved by the scientific advisor

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marked in such a way that the mark crosses both the attached item and the notebook page (i.e. the investigators initials).

11. Scientific experiments often generate large amounts of data, making their inclusion in hard copy laboratory notebooks unrealistic. In such a case, **large data files can be saved to any appropriate electronic medium such as read-only CD's** or to volumes on a local or central **server**. They must be **cross-referenced** to the primary hard copy laboratory notebook. When possible, images should be scanned, saved as a pdf document, and written to a read-only CD. Data have to be date-time stamped and included in a table of contents on the CD, perhaps in the form of a pdf, Word or Excel document. This provides an efficient method to determine what documents and data reside on the CD. Either way, the investigator must cross-reference existence of the data to the hard copy laboratory notebook. Importantly, backups of all electronic records have to be available as shown in the sketch below.



- 12. Summaries of Lab-meetings, "Dataclubs" and structured research discussions must be recorded in sufficient detail to allow reconstruction of the content and important contributions of individual participants.
- 13. **Graphs** have to be labeled clearly including a title, labeled axes and units. **Measured data points** should be clearly visible even if a line has been interpolated through the data points. **Tables** must have column headings and units.
- 14. After accomplishment of each experiment, the senior investigator should sign and date a notebook page as soon as possible.

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Electronic laboratory notebooks

Electronic laboratory notebooks face the same requirements as hard copy laboratory notebooks. Records must be sufficiently detailed and clear to allow someone "skilled in the art" to recreate the work and to conduct additional work without the direct assistance of the original researcher. What was done, why it was done, who suggested it, who did it, when it was done, what were the results (positive or negative), and what conclusions were drawn has to be recorded. An electronic backup must be maintained.

Storing laboratory notebooks

- 1. When not in use, notebooks must be kept in a central location, preferably in a locker.
- 2. Notebooks should be numbered in a consecutive order or consecutively under each scientist's name and unique initials.
- 3. When complete, notebooks should be reproduced, if possible on microfilm or other suitable means, and securely stored at a separate location.