Guidelines for keeping Laboratory Notebooks

Laboratory Notebooks

Laboratory notebooks are vital documents for the recording of experiments and ideas. They provide evidence which may be required to protect patent rights and they may be required by regulatory authorities to support applications to market new medical products. The books contain confidential information which must be protected from both theft and physical loss or damage. It is essential that books are –

- correctly completed, dated, signed and witnessed
- stored safely and securely while in use
- accessible if examination is required in the owner's absence
- duplicated
- archived securely and promptly on completion

Source of Laboratory Notebooks

Laboratory notebooks are available from the main School Office. Only the bound, books issued should be used for the recording of experiments and ideas. Loose leaf binders, such as ring binders and lever arch files, should be used for the binding of loose sheets which are too bulky to stick in lab notebooks. Avoid the use of box files.

Security

Laboratory notebooks (and copies) and associated loose leaf binders contain confidential information, the destruction or theft of which could harm the Inventors. They should not be left lying unattended or open on desks, especially if there are workers not bound by a Confidentiality Undertaking, visitors, engineers or representatives in the laboratory.

Storage

Overnight, and when not in use for the recording of experiments or the retrieval of data, laboratory notebooks should be stored in a safe, secure location which usually means locked in a (preferably fireproof) cabinet close to the workplace. The location of notebooks should be known to the supervisor to facilitate access in the absence of the book's owner.

Laboratory notebooks should never be left on desks overnight nor should they be stored in combustible drawers in a laboratory or office. Books can be severely damaged by water as well as fire so the storage location should be considered carefully. For example, it would be unwise to site a book storage cabinet next to a solvent store as, in the event of fire, it might be the target of high pressure water jets aimed at preventing the spread of the fire.

Associated data in loose leaf binders cross referenced to laboratory notebooks should be stored under the same rigorous conditions of security and physical safety.

Guide to Writing Up Laboratory Notebooks

Laboratory notebooks have several functions -

1. They provide a record of experiments in sufficient detail to enable experiments to be checked and even repeated by another individual who was not involved in the planning of the original experiment.

2. They provide evidence of the 'date of invention' for US patent purposes subsequent to the implementation of the GATT treaty of 1995. The book should provide an unambiguous record of all steps in the discovery process required by US patent law, which are:
    a) conception of the invention - ideas should be recorded in the books as well as actual procedures
    b) reduction to practice
    c) pursuance with due diligence
    d) application

The date of the conception is, of course, crucial but without the rest there is little chance of being granted inventorship under swearback. Rigorous standards of reporting and witnessing are needed to ensure that intellectual property can be secured under US patent law.

3. They may be required for examination by Drug Regulatory Authorities to support applications for licences to market new products

4. In conjunction with the School's COSHH Risk Assessment Forms they provide a record of the use of hazardous substances - both identities and amounts of substances should be noted where possible as well as how they were handled (the safety precautions employed)

5. In conjunction with the School's COSHH Risk Assessment Forms they are a record of the fact that you made an assessment of the hazardous substances used and the risks of carrying out the experiment before starting. This is a requirement of the UK Health & Safety legislation (COSHH)

Notebooks

To satisfy the US Patent Office criteria, notebooks must be permanently bound and have continuously numbered pages printed in them. Books should be numbered and (cross-) references should be given in the format AWL-0003-17-4 (Book 3, page 17, line 4). A line reference will often not be necessary. Generally, a notebook will only be completed by the investigator to whom it is issued, however, in cases where the responsibility for experiments is shared, multiple authorship is allowed provided there is a properly constructed signature index of authors in each book. This should provide the necessary continuity when more than one individual is involved in an experiment and where book ownership is transferred.

Loose leaf binders may only be used for spectra, charts, printouts, etc. which are too large or too bulky to glue into the notebook. There must be comprehensive cross-referencing both in the notebook and on the loose leaves. All loose sheets must be dated and signed and witnessed to validate the loose bound material. It is helpful to associate loose leaf binders with no more than one specific laboratory notebook.

Ink and colour - All writing must be in permanent ink, preferably using a black ball-point pen. Pencil and non-permanent ink must not be used. Coloured inks may be used to improve clarity but low contrast colours should be avoided where they do not photocopy well.

Thermal paper - Printouts on thermal paper fade with time and are thus not permanent. They should be signed, dated, witnessed and photocopied before pasting into the notebook. The original must be stored with a photocopy. Both copies should be fully cross-referenced to each other.

Handwriting - All writing must be legible and unambiguous. English in the past tense should be used.

Indices

The notebook should have a **Main Index** at the end of the book which lists -

- experiment number
- date of experiment
- A brief description of the experiment, the programme or project for which it was carried out and the identity of any experimental compounds used in order to act as a quick reference

An entry should be made in the Main Index when starting to write up an experiment so that there is an immediate record of what has been done. Experiments should ideally be written up as the experimental work is done. Making rough notes to be transcribed later is not considered good practice.

In addition to the Main Index, the **Non-Standard Abbreviation Index** at the front of the book should be completed at the time the abbreviations are used. All signatures, authors and witnesses, appearing in the book should be registered in a **Signature Index** at the front of each book.

Signature - As each page of the notebook is completed, it must be signed and dated by the author.

Witness - Each completed page must be signed by a witness who is capable of understanding the work but who is not directly connected with it, i.e. not likely to be a co-patentee, therefore preferably not working on the same programme. Books should be witnessed at least weekly. No changes or insertions should be made after witnessing. If this happens, the changes must also be formally signed, dated and witnessed.

Empty Space - All pages must be filled completely. Any empty space on a page must be scored through to prevent additional material be added.

Errors - Errors may be corrected as long as they are identified, explained and the amendments are signed, dated and witnessed. The original text must remain legible. The use of correction fluid or any obliteration of the error is strictly forbidden. Pages must never be removed from a book and nothing may be pasted over original text.

Finished books - When a book is considered finished or its use is discontinued, the page after the last entry must be marked to indicate that the book is discontinued. All subsequent pages must be scored through to prevent further use. The book may be passed to a new author provided the change of ownership is documented and the Signature Index is completed accordingly.

Guidelines for Writing Up Experiments

A report should consist of the following sections -

- Identification - Programme, Title of experiment
- Risk Assessment
- Material
- Methods. This may include an introduction to the work
- Results including data and spectra
- Conclusion. This should be apt, which means 'to the point' and 'not ambiguous'

Identification - Date, experiment number, the location where the experiment was carried out and the title of the experiment. The location is important as this information could be used in the future to trace the author or anybody else who might have been exposed to chemicals that were used in that environment at that time.

Experiment numbers should be unambiguous and systematic. For instance, they might usefully be initials and a sequential number (e.g. DEB45). This facilitates tracking of experiments and associated data.

The title of an experiment should indicate to the reader the nature of the experiment, the identity of any specific assay systems used and give fully the identity of any experimental compounds involved.

COSHH Risk Assessments - These are required to comply with UK Health & Safety legislation. The risk assessment should be completed on the School COSHH Risk Assessment Form. This should include the necessary statements that show that the author has considered the hazards presented by the chemicals, equipment and procedures that will be used during the experiment and also by the amounts used and the ways in which they are handled and disposed. It is helpful to have Standard Operating Procedures (SOPs) or Systems of Work (SOW) which can be referred to in Risk Assessments. The COSHH Risk Assessment should be bound into the lab book or cross referenced to the users file of Risk Assessments.

Materials - Any substance used which is not fully described in a SOP or SOW must be recorded. If a SOP or SOW does not mention amounts and/or hazards, these must be recorded in the materials section and the risk assessment. Experimental compounds particularly must be fully and explicitly documented for weight used, batch or charge number, volume of solvent and, if appropriate, the concentration of the resultant solution in both mg/ml and molar units. This is to facilitate checking. If a stored solution of an experimental compound is used, the fact that it was prepared by someone else and stored should be recorded. The date on which it was prepared, by whom (if possible) and an estimate the volume of solution handled should be recorded.

Methods -

An **introduction** to the work may be included as a preamble to the methods section in order to explain the aim of the experiment.

For a chemical experiment, the experimental description should be written out if full and not just referred to an SOP. The aim of the record should be that a less experienced person than the author should be able to repeat the experiment from the notes. Use standard English and recognised scientific abbreviations. Any non-standard abbreviations

or trade marks must be recorded in the Non-Standard Abbreviations Index in the notebook.

Results - Whenever feasible, copies of all raw data such as instrument printouts should be stuck in the book with permanent adhesive (i.e. an adhesive where removal of the material from the book would leave visible evidence of such). Adhesive tape should not be used as this degrades within the time periods concerned, 20 years or more, and can lead to the loss of the data. Where data is too bulky to stick into the notebook, there must be a clear cross reference to the location of stored raw data material which itself must be clearly and fully labelled, signed, dated and witnessed. Printouts of calculated and consolidated data should also be stuck in the book. Reference should be made to any specific computer procedure or templates used and their location, preferably stored centrally on a shared drive accessible on a read-only basis, if such details are not covered by a quoted SOP. When sticking data records into a notebook, there should be no overlays or folded sheets. This is not compatible with standard photocopying. Ideally, all material on a page should be within any printed margins and must not obscure the printed page number or the signature panel.

Conclusion - The conclusion should be recorded on the basis of what the experiment has demonstrated. This may be as simple as reporting the successful synthesis of the target compound. It may, however, require some interpretation and explanation of data, spectra or analytical results. It may be that the results were not conclusive, in which case it will be necessary to explain why doubt exists and to offer advice for future experiments which might be done to obtain a conclusive result. Results of experiments done which are considered to be negative in outcome must be recorded; the results are just as valuable as positive ones. Any definite conclusion drawn must be on the basis of the data presented and must not represent unjustified speculation or wishful thinking.

Storage

Laboratory notebooks should not be removed from the work premises except in exceptional circumstances. When not is use and for overnight storage, notebooks and associated data files should be stored in a safe, secure location. This will usually mean locked in a fireproof cabinet provided conveniently close to the workplace.

Archiving

Laboratory notebooks and associated data files should be securely archived and retained for at least 20 years after completion.