TECHNIQUES IN MOLECULAR BIOLOGY – LABORATORY NOTEBOOKS AND SOPS

Laboratory Notebooks. As scientists we understand the value of maintaining quality laboratory notebooks. Notebooks are daily records of every experiment you do or that you are planning to do. Notebooks contain your data whether good or bad, observations from your experiments, and form the basis for every scientific paper you write. Finally, we use notebooks as a record that allows successive scientists from your laboratory to reproduce your results and advance the project. In the bioscience industry, this understanding is expanded to include the notebook being a vital record of your work for patent purposes and protecting intellectual property. For example, notebooks are legal records for documenting drug, biologics, and medical device research under FDA guidelines. The other aspect of a laboratory notebook that is not always considered in either industry or academia is the fact that if allegations of fraud are brought against published or patented research, your laboratory notebooks will be used to validate your findings.

Electronic Laboratory Notebook (ELN). A significant number of processes including patenting, protecting intellectual property, QA/QC, GLP and GMP require extensive recording and carful control of access and data management. Many biotechnology and pharmaceutical companies use electronic laboratory notebooks. There is no standard format for ELN (otherwise known as information management systems) and over 20 companies currently support or license software for their ELNs. Features of ELNs not found in standard academic or paper laboratory notebooks include: real-time monitoring of data and restricted changes by managers, live links to established protocols or SOPs, controlling workflow, and the ability to allow clients access to data mid-stream of a project. Format for uploading and securing data, figures and databases widely varies and depending on the project and company may include additional security and supervision elements. An additional feature of some ELN includes tracking of reagents use, batch and inventory management to ensure stability and life span of reagents and samples.

Standard Operating Procedure (SOP). The FDA defines an SOP as a written method of controlling a practice in accordance with predetermined specifications to obtain a desired outcome. In regards to equipment use, SOPs give precise instructions on how a piece of equipment is to be used, maintained, and how the use and maintenance are to be document to ensure the validity of the outcome of measurements. In regards to experiments, the development of and SOP is part of a standard documentation process that involves development of an experimental protocol, the finalization of the details in an experimental method, and the final expression of how the experiment will be performed every time it is used in an SOP. While the terms experimental protocol and experimental method are frequently used interchangeably in academic research laboratories, this is not typically the case in an industry environment. An experimental protocol is the initial design of how to do a specific experiment and can be modified in an effort to optimize results. The protocol will be altered until the ideal process is identified. Once this experimental protocol has withstood the test of time it will be termed an experimental method. This experimental method is then presented, commonly in a checklist format, as part of an SOP. The experiment SOP will reference all of the equipment that is used for the experiment and the SOPs for those equipment items to ensure that each experimental step is done in the same fashion no matter which trained employee is doing the experiment.

Good Laboratory Practice (GLP). The FDA defines GLP as a quality system concerned with the organizational process and the conditions, under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. GLP also referred to as current GLP (cGLP) to imply the most current updates of GLP. GMP was developed by regulatory bodies including the FDA, EPA, and WHO to ensure that research submitted to them was not only executed in a proper fashion, but that the research was adequately documented so that any skilled scientist could follow the documentation to replicate the outcome of the experiment. This level of

documentation is substantial and ultimately increases the cost of doing the research.

Good Manufacturing Practice (GMP). GMPs mean the requirements found in the legislations, regulations, and administrative provisions for methods to be used in, and the facilities or controls to be used for, the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess. Additionally, GMPs are that part of quality assurance which ensures that products are consistently produced and controlled to quality standards.

Quality System / Quality Management System. A quality system is an organizational structure, procedures, processes, and resources needed to implement quality management. Quality management includes all activities of the overall management function that determine the quality policy, objectives, and responsibilities and implement them by such means as quality planning, quality control, and quality improvement within a quality system. The FDA requires that a quality management system must be in place in all companies that produce medical devices, pharmaceutical compounds, and biologics to ensure that their products consistently meet applicable requirements and specifications.

Why have a laboratory notebook? Isn't this just busy work? Don't worry, I'll remember what I did in lab. I'll just write down my results on scratch paper and fill in the details later. We have all made these comments about laboratory notebooks. Lab notebooks are not the students (nor the professors) favorite part of laboratory or research classes. However, communication is an essential part of conducting laboratory experiments. We gain practice in keeping notebooks in classes so we know how to do it when we work in research laboratories. Much of the value of collecting experimental data is lost if proper records are not kept. If methods and results are not clearly written and recorded, this information cannot be effectively transmitted to other scientists (including your professor). Notebooks contain your data whether good or bad, observations from your experiments and form the basis for every scientific paper you write. Notebooks are legal records for documenting drugs, biologics and medical device research under FDA guidelines. The following guidelines should be strictly adhered to for the recording of laboratory exercises.

Your laboratory notebook should be an accurate record of what you do in the lab, and should contain notes and calculations as well as appropriate comments to the lab your working on. ***A major function of a lab notebook is to allow another competent scientist to reproduce exactly your experiment.***

Your notebook will be graded based on the formatting (shown below), completeness and the statement in bold above. NO grade will be assigned for neatness. However, if I can't read the notebook then I cannot reproduce the experiment!

Finally, when taking notes for the lab (lecture or self made notes) or when doing protein structure work and bioinformatics searches, these should each have their own entry in the lab book.

A. **Experiment Number**

- In the upper right hand corner of each page of your notebook you should indicate the experiment number.
- Experiment numbers can be given in a number of different ways.
- I recommend using two or three letters then a number. For Example:

	MT1	Molec Tech Lab I Experiment 1
or	BTT3	Betty T. Tube Experiment number 3

B. **Date**

- The date should be given in the upper right hand corner of each page of the notebook, immediately below the experiment number.

C. **Title**

- Use an intelligent title, not just the name of the experiment copied from the laboratory manual. Pick a title that describes the content of your work.

D. **Introduction/Purpose**

- This section should include a two or three sentence statement of the purpose(s) and objective(s) of the exercises being performed.

E. **Procedure / Protocol or Methods**

- Write a description of procedures used including any deviations from the information presented in the laboratory handout.
- If there is a published exact protocol, then reference the protocol or procedure AND include a simple outline, flow chart or description of the referenced protocol. DO NOT PRINT AND TAPE the protocol into the notebook.
- When you have to repeat a routine operation several times, such as a protein assay, you can skip the details and refer to the specific page in the notebook where the procedure was originally described.

The title, introduction/purpose and materials and methods sections should be completed before coming to lab. (Deviations from the information presented in the laboratory handout will be recorded as you perform the laboratory experiments)

F. **Data and Results**

- All data and observations that are generated should be recorded in your laboratory notebook at the time of the exercise. This should include recopying any tables, graphs, formulas or other information from the laboratory manual. Also, tables of the data collected that day and graphs of that data should be included if appropriate. This section should include all calculations, averages and corrections to the recorded data.
- All information should be neatly presented with graphs and tables labeled appropriately. Graphs can be prepared using the computers in the laboratory and then taped into notebooks.

G. **Discussion and Conclusions**

- This section should include any interpretations, conclusions, or suggestions regarding the results of that day's exercise. A discussion of the expected results

and why they were or were not obtained should be included. THIS IS NOT A SUMMARY OF EVERYTHING THAT HAPPENED DURING THE EXPERIMENT THAT DAY. THIS IS A DISCUSSION OF THE DATA AND FINAL RESULTS.

- A good discussion might include:
    1. What were the major points illustrated by the data?
    2. Do the results agree with previously published works?
    3. Is the data contradictory in itself?
    4. Does your research have potential for follow-up experiments?
    5. Do your results support or disprove your hypothesis?
    6. Are your results dramatically different than what was anticipated and if so why?

H. **References**

- Include any references that were consulted for the experiment or cited in the report. Minimally, this should include your laboratory manual.
- References should be presented in alphabetical order by the last name of the first author.

Other Notes

1. For this lab you will need a bound, ruled notebook. Using a spiral bound book is not acceptable. The pages must be numbered and no pages should be removed. Dedicate this lab book to this class, only.
2. Use only pen.
3. If mistakes are made in recording information into the notebook, do not erase or use white out. Instead, draw a line through the mistake and then continue recording the correct information.
4. Leave two to three pages at the beginning of the notebook to establish a table of contents as the book is filled.
5. Since this is a course, taking notes in the laboratory notebook is allowed. Simply give the notes a number and a title.
6. Number and label all tables and graphs with a title indicating what they are intended to represent.
    A. Tables are numbered and titled above the table.
    B. Figures are numbered and titled below the figure.
7. Do not use different color pens or pencils in different parts of the notes or figures. Colors do not photocopy effectively.
8. Tape computer-generated graphs into your notebook.
9. This is not a personal diary and references to that affect should not be included.
10. Show your calculations in the data/results section. Often if an experiment does not work it can be tracked down to a miscalculation.
11. Remember your results from the exercise are important. You are not being graded on the outcome of experiments therefore you should strive for the most accurate and intelligent representation of your data possible.
12. Don't leave blank spaces and use space efficiently.
13. Taping or gluing printed methods from the web does not count as a written protocol. You can certainly refer to it, but do NOT tape it in.