

Excerpts from
Writing Effective GLP Documents

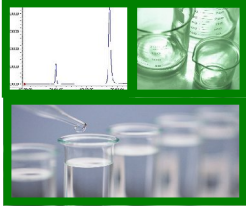
GLP Training Workshop – March 2010

Presented by Celeste Rose, RQAP-GLP

RoseTECH Consulting, Inc

www.rosetechconsulting.com

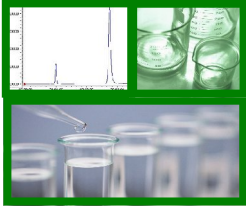
*This training workshop is sponsored in conjunction with the
FDA compliance learning community of enKap www.enkap.com*



What is “Technical” Writing

- Defined purpose
- Knowledge on topic
- Reader focused
 - Clear organization
 - Help reader find important info easily
 - Meet needs of reader

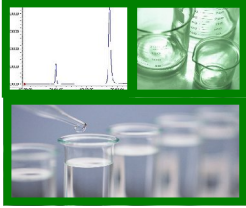




Who is the Reader?

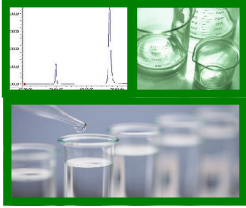
- Why am I writing this document?
 - Who are the intended readers?
 - Of protocols?
 - Of amendments?
 - Of deviations?
 - Of reports?
 - Other documents (e.g. SOPs, correspondences)
- What is expected of the reader?
- What does the reader expect?





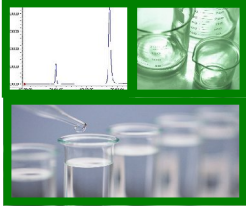
Purpose of the Reader?

- Why is the reader reading the document?
 - What questions does the reader need answered?
 - What action is the reader going to take after reading the document?
 - What inappropriate or incorrect action might the reader take based on a misunderstanding/misperception of the document?



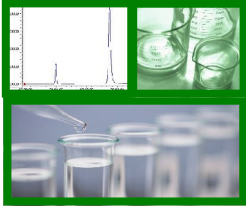
ABCs of Organization

- Format ABC
 - Abstract
 - Overview introduction, summary of main points
 - Body
 - Procedures, details, results and discussion
 - Conclusion
 - Wrap up
 - Summary of results/main points
 - Next steps, if any



Presentation Formats

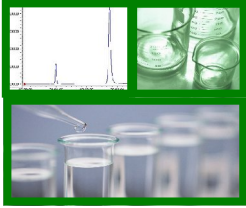
- Choose an appropriate format to present
 - Instructions (e.g.)
 - Procedure step numbering 1,2,3...
 - Flowcharts, decision trees, diagrams
 - Parameters (e.g.)
 - Tables
 - Bullet lists
 - Results (e.g.)
 - Tables, figures, charts



Effective Technical Writing

- Write for the Reader Not for Yourself!
- Know your Reader(s)
- Record and write for the “Reader”
- Reconstructibility is Key
- GLP study has a life after study conduct

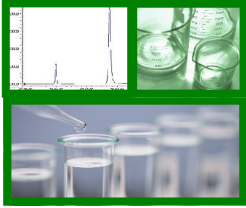




Protocol

- A well-written protocol sets the platform for study reconstructibility

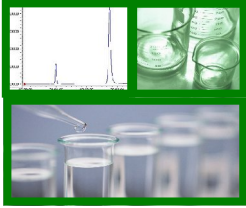




Deviations

- Documentation of deviations is a useful tool:
 - Describe unusual or unexpected events or observations
 - May be critical in explaining “anomalies” in data and results
 - Support reconstruction of study

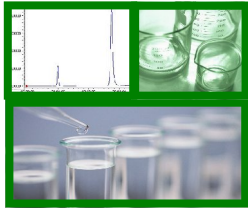




Phase Reports

- Issues to consider when writing reports
 - How well does SD understand study phase subject?
 - Does SD have luxury of visiting/viewing operations?
 - Communication between SD and PI/CS is important

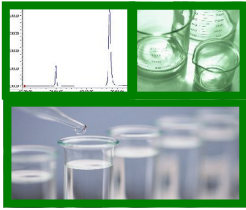




Reports

- Write for the Reader!
 - Use clear wording and organization that meets the needs of the Reader
- Be concise
 - Avoid wordy phrases
 - Cut out extra words
 - Be direct
 - The data seem to indicate...
 - The data indicate..

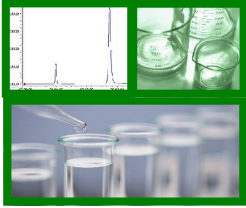




Raw Data

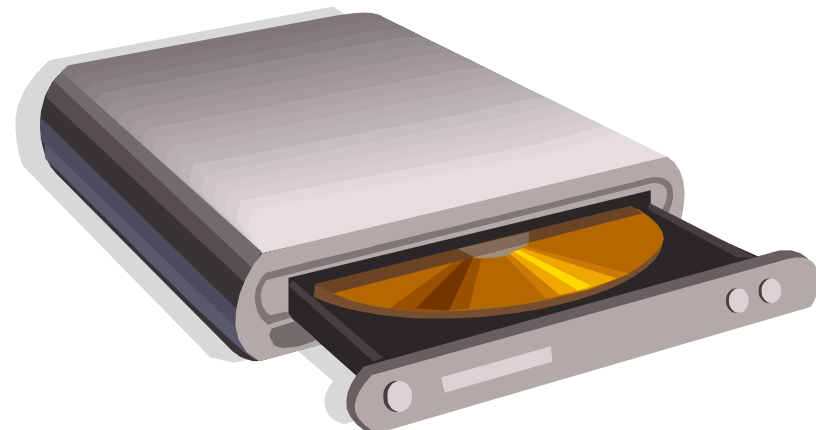
- GLP Definition of Raw Data
 - Any worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of study & necessary for the reconstruction and evaluation of the study report

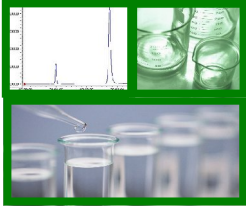




Data & Documentation

- GLP requirements pertain to:
 - Manually-recorded (hand-written) records
 - Electronic (computer-generated) records

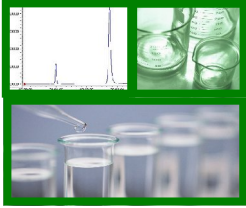




Checklists

- Checklists
 - List and identify tasks
 - Reduce chance of omissions
 - Document tasks completed
 - Affirm operation was performed





Reconstructibility

- GLP study has a life after study conduct
- Record and write for “reader”
- Study understandable/reconstructible
 - By others not involved with study
 - By You several months/years from now

