

Laboratory Quality Systems Homework # 1

GENERAL SOP GUIDELINES/CHECKLIST

- ☐ **Purpose**
Explain SOP's intended objective.
- ☐ **Scope / Field of Application**
State the range of activities and/or personnel the SOP applies to, as well as any limitations or exceptions.
- ☐ **Definitions**
Define words and acronyms that people reading the SOP would not generally know and that would require clarification. If a definition is needed, and one exists in the regulations, use the regulation's definition.
- ☐ **Responsibilities**
Identify personnel (by title) responsible for complying with the SOP.
Identify personnel (by title) responsible for assuring the appropriate personnel are trained on the SOP.
- ☐ **Materials Required**
List all material required to complete the procedure including form. Include Model Number and Manufacturer's name for equipment.
- ☐ **Procedure**
Explain the procedure in simple steps. Describe *what* to do, not *how* to do it.
State who completes each step and how the activity is documented to be certain that whoever is performing the procedure can prove that they have done it.
- ☐ **Documentation**
List the Quality Records to be generated and the person responsible for generating and maintaining them.
- ☐ **Reference Procedures**
If the procedure described in the SOP is follows or is based on a standard procedure or method, list it here.
- ☐ **References**
List related SOPs, any supporting documentation necessary to understand and correctly follow the procedure, and any applicable regulations and regulatory guidelines.
- ☐ **Review and Revision**
State how often the SOP is reviewed and/or under what circumstances it is to be revised.