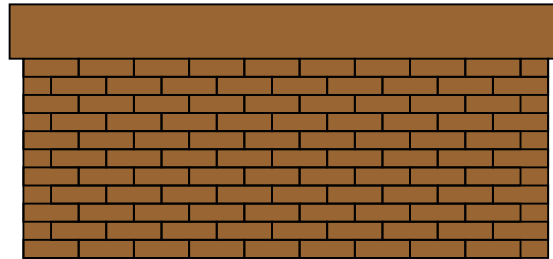


Outside of the Walls

Protocol & SOP Changes & Audit Checklists



The Protocol

- It tells what is going to be done...
- it **DRIVES** the study
- It should be signed & dated by the Study Director (and approved by the Sponsor)
- Become familiar with it



The Protocol

- Planned change “Amendment”
- Must be documented with reasons
 - *Recommend*: Show original information (if any) & what it was changed to / reason
- Only the Study Director can alter the ‘direction’ of the protocol
- Signed / dated by Study Director
- Filed with the protocol
- Should be communicated to all applicable staff

The Protocol

- Amendment
 - With advanced notice, some things can be documented as an amendment before they occur
 - Example: unforeseen schedule conflict for a timed harvest
 - **If approved by the Study Director**

The Protocol

- Unplanned change “Deviation”
- Must be documented with reasons & communicated to the Study Director
 - *Recommend*: Show original information, what occurred/reason, impact on study
- Signed / dated by Study Director
- File with the protocol

The Protocol

- Remember...
- The importance of “notes” in protocol changes
 - Emails, telephone logs
- These should be signed / dated & included in study file

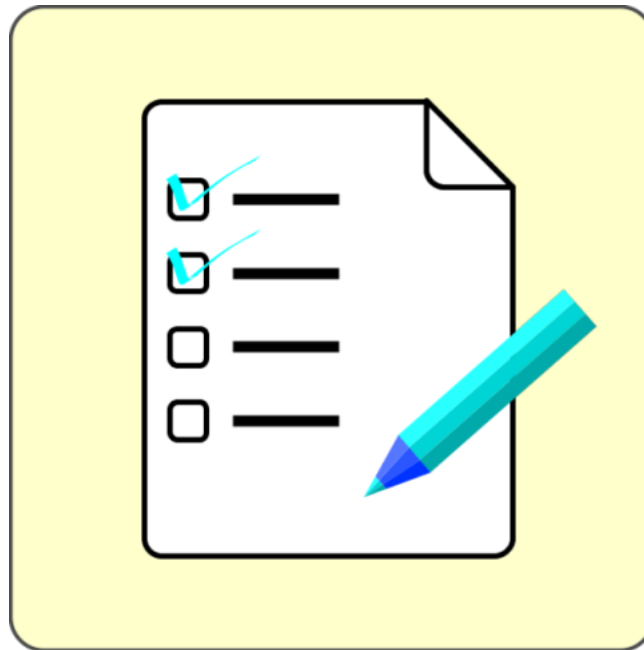
SOPs

- Unplanned changes “deviations”
- Must be documented
 - *Recommend*: Original information, what occurred & reason, impact on study
- Authorized by the study director
- Filed in the raw data

SOPs

- Planned changes “Amendments”
- Must be documented with reasons
 - *Recommend*: Show original information (if any) & what it was changed to / reason
- Authorized by Study Director
- Filed with the raw data
- Should be communicated to all applicable staff
- Significant changes should be approved in writing by management – revise the SOP

Checklists for Auditing



Checklists for Auditing

- Useful auditing tool
- Checklists can be used for :
 - Protocol reviews
 - Data / notebook reviews
 - Final report reviews
 - Phase audits



Checklists for Auditing

- They can be general
- Use the GLPs to develop your checklist
- They can be specific
- Use the GLPs & your SOPs to develop your checklist



Checklists for Auditing

- What can be on a checklist???
- Identify what you are auditing
 - Study title
 - Study number / Project number
 - Phase or activity inspected
 - Date of Audit
 - Auditor
 - PI & Person performing the work



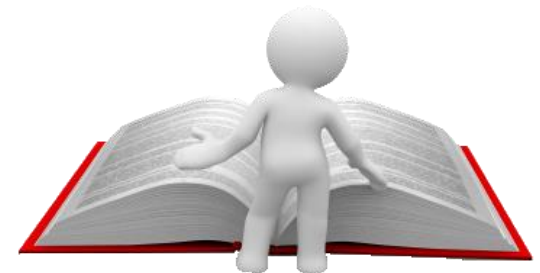
Checklists for Auditing

- Protocol Number
 - Do you have a complete copy of the protocol?
 - Is the protocol signed / dated?
 - Do you know what the QA responsibilities are per protocol?



Checklists for Auditing

- SOPs
 - Identify what SOPs will be used for the audit
 - Are they adequate in topic and scope of the work
 - Are they approved / reviewed at the appropriate frequency
 - Are they available to the appropriate staff
 - Were the SOPs followed



Checklist for Auditing

- Personnel

- Received GLP training

- CVs, job descriptions, & training records / read & understood SOPs are on file & up-to-dates

- Data recorded properly





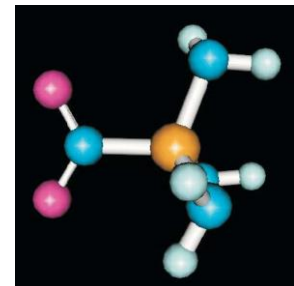
Checklists for Auditing

- Equipment
 - Identify equipment used
 - Has it been verified / calibrated / cleaned as per SOP
 - Logbooks / records are up-to-date



Checklists for Auditing

- Test Substance
 - As per protocol / COA /COC
 - Labeled (name, batch #, expiration date, storage conditions) & handled properly
 - Stored properly per protocol & label



Checklists for auditing

- **Test Substance** (continued)
 - Usage documented
 - Preparation for application
 - Carrier / vehicles / adjuvants documented
 - Labeled (name, lot #, expiration date, storage conditions)
 - Application



Checklists for Auditing

- Test Systems
 - As specified in the protocol
 - Maintenance



Checklists for Auditing

- Control & Treated Plots
 - As per protocol (size, layout, location...)
 - Identified
 - Location identified / documented
 - Pesticide history / maintenance chemicals documented



Checklists for Auditing

- Phase audited (application, sampling, ...)
 - Study specific requirements
 - List important aspects of these activities
 - documentation



Checklists for Auditing

- Have space for
 - audit notes
 - Audit findings / observations
 - Responses to QA findings / observations
 - Signatures / dates (coversheet)



- Remember to make it work for you!

Thank you

