NAME: EDE ADE EDWINA

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QUESTION : Using the protocol or study plan of GLP requirements, what are the points that is likely to be important in the experimental design for a typical animal toxicity study?

ANSWER

SOPs for inspections and for audit reports should be prepared in dialogue with staff.

• The inspector/auditor should prepare for the inspection/audit. Usually this means reviewing the protocol, applicable SOPs and past inspection findings beforehand.

• The inspector/auditor must follow all rules of access, safety and hygiene and must not disrupt the work.

• The inspector/auditor must allow sufficient time for the inspection.

• Check lists may be used, as necessary. Adherence to a check list is no guarantee of completeness but it is useful for training and as a guide. Also, check lists enable management to approve QA methods and coverage, and provide technical staff with a means of self-checking. Check lists are usually established formally and updated over time. However, a check list raises the risk of missing an unexpected finding.

• At the end of the inspection, or at least before a report is issued, the inspector should discuss all problems with the persons inspected. Any error (e.g. dosing error, animal ID) should be pointed out immediately,

• Findings/comments should be clear, specific and constructive. Sometimes solutions to problems can be suggested by QA.

• Comments should be constructive. One way of ensuring this is to propose a solution to each problem reported in the inspection report.

• The report circulated to management (with or without a separate summary) should include comments and responses. Rules for the writing, approval, distribution, and archiving of inspection/audit reports as well as arbitration procedures should be included in the SOPs.

• As a general rule, internal QA inspections and audits target events and organization, not people. The more problems uncovered and resolved the better the level of quality.