1 Purpose

To define the process to be used for the frequency and audit of critical phases within a non-clinical safety study.

2 Scope and Applicability

This procedure may be applicable for all R&D GLP QA staff and will be used in the compilation of a program to identify audits to be undertaken for non-clinical safety studies and study parts for which compliance with GLP is claimed.

3 Definitions

3.1 Critical Phase: A study specific procedure, during the experimental phase of, a non-clinical safety study that has been identified for QA involvement. Critical phases are defined in Appendix 1.

3.2 Study based audit: The audit performed on a critical phase during the conduct of a specific study.

3.3 Study Part: The defined set of activities on a study for which a Principal Investigator is responsible.

3.4 Study type: Non-clinical safety studies grouped by scientific discipline or resource group. Study types are defined in Appendix 1.

4 Responsibilities

4.1 GLP QA Head

Head of GLP QA is responsible for ensuring that adequate study based audits are conducted to assure management that GLP compliance is being maintained.

4.2 QA Advisor

Any trained member of GLP QA may undertake study based audits. Advisors are responsible for the planning/scheduling, conduct, reporting and follow-up of an audit, and for maintaining QA records.

5 Procedure

5.1 Frequency of audits

All critical phases listed in Appendix 1, will be audited every 3 months, when they are being conducted. For all study types, critical phases ongoing at the same time as dosing will also be audited at that time. Dosing will be audited every 3 months for long-term studies. Any phase that is non-routine, e g non-routine

A copy of the study plan and any amendments, the previous QA report, where relevant and pertinent SOPs shall be read before or during the audit.

All GLP and related issues will be discussed with the personnel undertaking the procedure at the end of the audit. It may be necessary to further clarify audit comments with the appropriate facility staff or Study Director or Principal Investigator prior to reporting. The advisor may also check that actions arising from relevant previous audits have been dealt with satisfactorily.

5.3 Checklist

Checklists are available as a general guide and do not form part of the audit records.

5.4 QA Report

A QA report will be generated according to the International Procedure for GLP QA reporting.

In vitro studies

ÅFormulation preparation/Dosing

Development DMPK& Bioanalysis

ÅFormulation preparation (14C studies)
ÅFormulation Analysis (14C studies)
ÅDosing
ÅBiological Fluids Sampling
ÅBiological Sample Collection
ÅSample Analysis

* Sample Receipt
* Sample Preparation
* Sample Analysis

(*) = only used at test sites where process audits are not conducted for these phases.

