not just those claimed in SOPs and management documentation.

5.2.3 Exit meeting:

1. At the end of an audit, a discussion will take place with the supplier or vendors QA and management to advise them of areas of concern and any requirements the sponsor would wish to have resolved and will appear in the report.

2. Issues of misunderstanding can be clarified and resolved where possible at this meeting.

3. This meeting shall also be used to indicate where the respective R&D QA staff is pleased with standards and practices.

4. Confirm any sponsor R&D actions requested.

5.3 Audit report

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

5.4 Quality Standard

It is expected that the key suppliers or vendors to have a recognized quality standard in place. If the supplier does not claim compliance with GLP, it is expected for them to have a documented quality system, eg. ISO 9000. As a minimum the following will be verified:

- Training of staff
- Responsibilities
- Documented procedures
- Maintenance of equipment
- Documented production
- Effective quality assurance

5.5 Closing of Audit

Upon receipt of a response, the lead QA advisor will check it for completeness and appropriateness and close the audit.

