

## Quality and Compliance Auditing

### 5.6.2 Major (Significant) Observations

“Deficiency with Company Standards, GXPs, and/or current regulatory requirements or expectations that provides a potentially significant risk to product quality, patient safety or data integrity. A Major Observation can also be a combination/repetition of Minor Observations that indicate a failure of system(s) and can potentially result in a significant observation from a regulatory agency.

A response indicating responsibilities and timescales of corrective actions is required.

### 5.6.3 Other (Minor) Observations

“Observation of a less serious or isolated nature that is not deemed Critical or Major, but requires correction, or suggestions given on how to improve systems or procedures that may be compliant, but would benefit from improvement (e.g. Good Practices seen elsewhere).’

Where possible references should be made to the regulations, guidelines or internal procedures to which observations relate.

### 5.7 Follow Up

Processes must be in place to ensure responses are reviewed for their adequacy /timeliness and their progress monitored. The audit should be kept ‘live’ until it is evident that corrective and preventative actions have been completed , or until a satisfactory response has been received from the auditee that corrective and preventative actions will be completed in an appropriate timescale. The audit may then be ‘closed’.

### 5.8 Report Retention

The security/distribution/retention procedures for audit documentation must be described in procedures. A separate log of audits undertaken is recommended.

### 5.9 Audit Program Review

The status of the audit program and the outcome of audits and follow up actions must be a regular item for the management meetings within an area.

It is recommended that Key Performance Indicators are defined and monitored for audit performance.

It may be appropriate to include corrective actions to critical and significant audit observations and/or trends within local Compliance Improvement Plans.