

**1 Purpose**

The purpose of this guideline is to define the concept of Quality and Compliance Auditing within the system of quality management and outline the roles and responsibilities for planning, performing, reporting and follow-up of audits.

**2 Scope and Applicability**

This Guideline is applicable to all pharmaceutical manufacturing sites, functions And departments undertaking work, or providing support services, required to meet Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) and/or International Organization for Standardization (ISO) standards.

**3 Definitions**

**3.1 Audit**

Note that, audits may assess: systems, processes, procedures, facilities, products, studies, reports, records and/or data for compliance with policies, standards, procedures, guidelines, regulations or regulatory submissions. Audits may assess both in-house and external activities. Audits may be planned, or undertaken on a 'for-cause' basis.

**3.2 Critical Observation**

“Deficiencies with Company Standards, and/or current regulatory expectations that provide immediate and significant risk to product quality, patient safety or data integrity, or a combination/repetition of major deficiencies that indicate a critical failure of systems.”

Immediate corrective action and reporting to Management is required.

**3.3 Major Observation**

“Deficiencies with Company Standards and/or current regulatory expectations that provide a potentially significant risk to product quality, patient safety or data integrity, or could potentially result in significant observations from a regulatory agency, or a combination/repetition of “other” deficiencies that indicate a failure of system(s).”

**3.4 Minor Observation**

Observations of a less serious or isolated nature that are not deemed Critical or Major, but require correction, or suggestions given on how to improve systems or procedures that may be compliant, but would benefit from improvement (e.g. Good Practice seen elsewhere).

clear to all involved.

Observations made during the audit should be discussed with personnel, preferably at the time they are observed, so that they are understood by all involved. At the end of the audit, a verbal summary must be given by the auditor. This should aim to balance positive feedback with any observations made.

## **5.6 Audit Reporting**

Audits must be documented in formal reports, preferably to a standard style/format. A clear statement of audit outcome must be included in the summary.

The report must be issued to an agreed circulation list, including management of the audited area, within a defined time period (commonly within 15 days), and should clearly include any observations that require written responses and the timescale for response (commonly within 15 days of receiving report).

All audit reports should be issued as a confidential document and the list of recipients kept to a minimum. The statement “This document is the legal property of the company. Its use is confined to the company employees. Use or disclosure of the contents outside the company, without authority, is not permitted.

(Accepted practice within the Pharmaceutical Industry has historically been that the content of internal audit reports would not normally be shared with external regulatory agency inspectors, although audit schedules/logs may be. However, some regulatory agencies are now asking to see actual audit reports as a means to ensuring any corrective actions identified are followed up adequately. Regulatory Agencies are also bound to confidentiality.

Audit Observations must be classified into Critical, Major (Significant) or Other (Minor) categories. For example:

### **5.6.1 Critical Observations**

“Deficiency with Company Standards, GXPs and/or current regulatory requirements or expectations that provides an immediate and significant risk to product quality, patient safety or data integrity. A critical Observation can also be a combination/repetition of Major Observations that indicate a critical failure of systems.”

Immediate corrective action and reporting to Management is required. All critical observations should additionally be reported to senior management via the formal Compliance Issue reporting process and where appropriate elevated to the functional continuous assurance process.