

INTERNAL QUALITY AUDITS**1.0 GENERAL**

- 1.1 It is the policy of the Company to implement and maintain procedures to conduct regular documented internal audits of the quality system in order to ensure that it remains in compliance with planned arrangements.

2.0 RESPONSIBILITY

- 2.1 It will be the responsibility of the Quality Assurance Manager to ensure that internal audits are carried out in accordance with the audit schedule.

3.0 REQUIREMENTS

- 3.1 The Company will implement and maintain procedures to ensure that all sub-systems within the quality systems are audited in whole or in part, at least once a year.
- 3.2 The frequency at which any particular system is audited will be determined by the Quality Assurance Manager and will be based on the status and importance of the activity.
- 3.3 Records of internal audits will be maintained
- 3.4 Auditors will be trained in the techniques of auditing and where advantageous will be independent of, ie having no direct responsibility for the function being audited.
- 3.5 Where necessary, either to maintain independence of the audited function or because of the need for a particular skill, auditing may be subcontracted to a third party.
- 3.6 Quality audits shall include examination of quality records and batch manufacturing records to establish conformance with procedures.
- 3.7 The results of all audits will be brought to the attention of the manager/supervisor responsible for the area or system audited in order for the corrective action to be agreed.
- 3.8 Corrective and preventive actions will be scheduled and confirmation that these actions have taken place on time will constitute part of the internal audit record.

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PREPARED BY: D TINSLEY	QA CHECK: AJ/TW	REG AFFAIRS CHECK: CB/IN	OTHER CHECK: J S GALLAGHER

3.9 Internal audit records will form part of the management review.

4.0 RELATED PROCEDURE

4.1 Internal Audit Procedure

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