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| 1.0 Scope |

1.1.  All Pharmaceutical activities are subject to an internal audit to ensure GxP compliance.

1.2.  The “Company” QMS is subject to internal audits.

1.3.  Not all internal audits will be scheduled. Some audits may arise following a deviation, complaint, change request, or at the request of senior management.

1.4.  Unscheduled audits will follow all relevant aspects of this procedure and additional internal audits references may be added to the original schedule when required.

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| 2.0 Department/Site Affected |

2.1. All personnel involved in GxP activities.

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| * 1. Objective
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3.1.  To ensure “The Company” processes and systems are in compliance with GxP guidelines.

3.2.  To ensure all findings from the internal audit are recorded and tracked through CAPA system.

3.3.  To provide senior management with oversight of the QMS performance.

3.4.  To provide the business with assurance that internal control systems are operating effectively, and audit findings are being used as a tool for continuous improvement.

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| 4.0 Risks |

4.1. Risks associated with this Standard Operating Procedure include but are not restricted to the following:

4.1.1. Internal Audit schedule not covering critical GDP activities and QMS procedures resulting in key processes and procedures not being audited.

4.1.2. Internal audit plan not robust enough to interrogate the “The Company” GxP systems and QMS.

4.2 Strict adherence to this Standard Operating Procedure should minimise all such risks.

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| 5.0 Terms and Definitions |

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| CAPA | Corrective and preventative action |
| Corrective Action | An action that is performed to immediately mitigate the impact of a current service delivery issue identified through a reported deviation or complaint. |
| Preventative Action | An action that is instigated to prevent the nature or cause of a reported deviation or complaint reoccurring |
| Pharmaceutical Activities | Products being shipped by Life Sciences and Healthcare customers (including pharmaceuticals, biologics and medical devices)  |
| QMS | Quality Management System |

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| 6.0 Responsibilities |

6.1 Responsible Person

6.1.1. The RP is responsible for ensuring an internal audit schedule is in place and all audits are carried out in a timely manner.

6.2 Internal Auditor:

6.2.1. Internal Auditors are responsible for ensuring a robust and fair audit is carried out and action arising from the audit is communicated to senior management and all relevant parties.

6.3 Senior Management:

6.3.1. Senior Management are responsible for ensuring the QMS is adequately resourced to support a robust internal audit program and to ensure audit findings are closed in a timely manner.

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| 7.0 Procedure |

7.1. Internal Auditors Training

7.1.1.  Internal audits are led by the Responsible Person or designee who have demonstrated through their academic qualifications, training and work experience that they possess the appropriate knowledge and understanding of the principles of internal auditing.

7.1.2.  Trainee Auditors shall be trained by the RP or designee in a form of internal audit shadowing. The trainee auditor will shadow and assist the RP or designee for a minimum of 3 internal audits. After the internal audit shadowing, the RP or designee will continue to carry out joint internal audits with the trainee internal auditor where they will observe the trainee auditor’s skills, style, process knowledge and GDP knowledge.

7.1.3.  The RP will continue to observe the trainee auditor until they are satisfied that the trainee auditor is competent to carry out internal audits on their own.

7.1.4.  The trainee auditors shall be confirmed as an internal auditor when the RP has signed off their training as being competent.

7.2 Internal Audit Schedule

7.2.1.  Within the first week of the calendar year, the RP or designee shall draw up an internal audit schedule for the year.

7.2.2.  The business processes that contain the highest level of risk shall be given priority.

7.2.3.  The RP or designee will agree a timeframe for QMS audit with a trained auditor before the internal audit schedule is signed off.

7.2.4.  The schedule will not determine specific dates for the audits. It will specify the month only.

7.2.5.  The proposed audit shall be completed within 1 month of the date agreed on the schedule.

7.2.6.  If an audit is completed outside of the 1-month grace period, a deviation must be raised and CAPA plans must be documented accordingly.

7.2.7.  The audit schedule shall be authorised/approved by the Director of Quality and Compliance or an authorised designee.

7.2.8.  The schedule must be approved and published at least 5 days prior to the first audit.

7.2.9.  The schedule must be version controlled to accommodate updates, as there may be circumstances where processes may have to be re-prioritised due to demand and resources and also to accommodate circumstances where a “for cause” audit is required.

7.2.10.  If there is a need to update the schedule or the schedule is not adhered to for any reason, a risk assessment must be completed to document the risks associated to the change in schedule or the risk imposed/introduced to the business/process by not adhering to the original schedule. This risk assessment shall be completed following Quality Risk Management Standard Operating Procedure (SOP-X).

7.3 Internal Audit Planning

7.3.1.  The audit date must be agreed by the RP and the relevant department manager at least 30 days prior to the audit being conducted unless it is the first audit of the year.

7.3.2.  Once a date has been agreed upon, the lead auditor (RP) must ensure that the audit is carried out as agreed. If this is not possible and the audit has to be rescheduled, provided it is within the same month as prescribed on the schedule, then this is acceptable. If the proposed date for the rescheduled audit falls outside the prescribed month, then the auditor has 1 month (from agreed date) to ensure the audit is carried out.

7.3.3.  Prior to the audit being conducted, the RP or designee must familiarise himself with the regulations and all documentation related to the process being audited.

7.3.4.  Where applicable, the relevant documentation shall be reviewed, and an audit checklist created prior to the audit taking place.

* 1. Internal Audit Process

7.4.1.  The audit shall be led by a trained internal auditor (RP or designee) and when required will be accompanied by another member of staff.

7.4.2.  The audit shall be hosted by the departmental manager or designee.

7.4.3.  On the day of the audit the auditor shall conduct the audit in an open manner.

7.4.4.  The auditor must ensure he/she has an opening meeting with the auditee to explain the purpose of the audit and the areas to be audited.

7.4.5. The audit will include the following:

7.4.5.1. Documentation review process;

7.4.5.2. Interviewing of the auditee (s) and other staff members;

7.4.5.3. General observations made during a tour of the relevant area;

7.4.5.4. The auditor shall review the current process against current approved SOP for compliance.

7.4.5.5. The auditor must ensure he/she conducts a close out meeting with the auditee explaining the findings, what the content of the report will be, agree on corrective/preventative actions and timelines for completion/action as per CAPA SOP (SOP-9).

7.4.5.6. Audit notes must be retained by the auditor until the final report has been approved, authorised, published and all follow up actions are completed.

7.4.5.7. If an internal audit is not completed as per the schedule, a deviation should be raised to record the non-adherence to the schedule and any risks introduced to the QMS as a result of not carrying out the internal audit according to the approved schedule. This should be done as per SOP-XX (Deviations and Nonconformities) and SOP-XX (Quality Risk Management).

7.5 internal Audit Classification

7.5.1. Audit findings are grouped according to their criticality to the GxP or other regulatory standard. The auditor shall reference the process being audited, the relevant SOP, and the GDP or other regulatory standard requirements.

7.5.2 The criteria for findings is:

 **7.5.2.1 Critical finding:**

1. Where there is a serious breach of GxP resulting in patient safety being compromised.

2. Where there is a serious breach of a regulatory standard that could compromise compliance.

**7.5.2.2 Major finding:** Where GxP or “The Company” systems are not routinely followed.
**7.5.2.3 Minor finding:** Where systems do exist but is insufficient or not fully adequate.

**7.5.2.4 Recommendation:** General recommendations to improve systems and processes.

7.6. Internal Audit Reporting

7.6.1.  Following completion of the audit, an audit report must be written within 5 working days of the audit being completed.

7.6.2.  A draft version of the report must be submitted to the auditee for review and comments using (FORM-Q012).

7.6.3.  Upon receipt of auditee’s comments, the audit report shall be finalised and submitted for management approval.

7.6.4.  The signed report shall be published, and copies distributed to the auditee, department manager, senior management and RP.

7.6.5.  Agreed CAPA actions shall be reviewed and corrective actions will be monitored for timely closure.

7.6.6.  Preventative actions shall be transferred onto the CAPA log and tracked for closure.

* 1. Internal Audit follow up and closure

7.7.1.  The RP must follow up and review the progress of the CAPA on a regular basis until closure.

7.7.2.  Monthly review of the audit findings will be conducted to ensure all actions have been closed off. Any open (overdue) findings will be escalated to senior managers.

7.7.3.  When CAPA actions have been completed, the RP must ensure all supporting evidence is provided to support the closure of the observation/findings. The evidence must be attached to the audit report for filing.

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| 8.0 Related Documents |

8.1. SOP-XX Deviations and Non-Conformities
8.2. SOP-XX Quality Risk Management

8.3. SOP- XX Corrective Action Preventative Action (CAPA)

8.4 FORM - Q011 – Internal Audit Schedule

8.4. FORM – Q012– Internal Audit Report

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| 9.0 Appendices |

None

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| 10.0 Attachments |

1. FORM-Q012-V01InternaAuditReportForm.docx
2. FORM-Q011-V01InternalAuditScheduleTemplate.docx

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| 11.0 Records and Retention |

11.1 All superseded controlled versions of this procedure must be retained safely and securely

11.2 Documents that are printed for reference purposes in hard copy will be valid for a 24hour period only.

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| 12.0 Document History |

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| Version Number | Version History |
| 1.0 | Original version of document |
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