GD022

Corrective Action and Preventive Action (CAPA) Guidance

PURPOSE:
To define the process to report quality system non-conformities using a CAPA, investigate their root cause, and prevent them from occurring (for preventive action) or recurring (for corrective action). In the context of this document, non-conformity can be any of the following but not limited to:

- Protocol non-compliance
- Protocol deviation
- Non-compliance with departmental SOPs
- GCP non-compliance
- Serious breaches of GCP
- Any of the above arising from inadequate training/experience of personnel
- Any of the above arising from procedural or logistical issues

For the purpose of Royal Papworth Hospital NHS Foundation Trust CAPA, non-conformities could be highlighted via any of the following means (but not limited to):

- Internal monitoring
- Internal auditing
- Externally requisitioned audit
- Regulatory inspection
- Mock inspections

PROCEDURE: Identify and record the non-conformity on the CAPA database in IQM:

All non-conformities should be recorded in a centralised system. If any of the above non-conformity requires a CAPA, this will be completed in IQM.

The non-conformity must be recorded by the QA team onto the CAPA database and, once agreed as detailed below, all further information must be entered in due course.

DETERMINATION OF ACTIONS REQUIRED:

Root cause analysis:

- Analysis must be undertaken by the persons responsible for the trial and the QA team to clarify the finding
- Discussion must agree all actions to be completed as detailed below
- The person responsible for completing agreed actions must be identified
- The deadline for completion of all actions must be agreed
- All findings/actions and dates are to be entered onto the CAPA database by the QA team

Corrective action:

- All actions that are required to **correct** the detected non-conformity or other undesirable situation found at Audit/Monitoring/Inspection.

- Includes investigation and correction of occurrences, there may be more than one cause of a non-conformity.

Preventative action:

- All actions that are required to **prevent** **re-occurrence of** the cause of a non-conformity or any other undesirable situation.
- There could be more than one cause for a potential non-conformity.

Communication:

If required, the non-conformity will be reported to the required personnel using the CAPA process form with clear instructions as to the person/s responsible for undertaking any corrective and/or preventive action, along with deadlines for actions to be completed. The Details from the process form will be transcribed in the CAPA in IQM and the CAPA process form saved within IQM.

REVIEW AND IMPLEMENT:

- Once the responsible person/s has completed all actions, the QA team must update the relevant CAPA in IQM and mark the entry as complete.
- If it is felt necessary to re-audit/re-monitor in order to ensure that the actions have been implemented into practise as preventative measures, then this will be discussed, agreed, and recorded on the database as being required.

RE-AUDIT/RE-MONITORING:

- Any required re-auditing/re-monitoring must be completed as agreed above and recorded in IQM. This may either be a stipulation of the original CAPA database entry in which case the re-audit/monitoring must be undertaken before the entry can be marked complete. However, the requirement to re-audit/monitor may also be agreed as a separate event that can be recorded on the CAPA database as a new event.

ROLES/RESPONSIBILITIES

Role	Responsibility
QA team	• Maintain oversight of auditing and monitoring processes • Maintain IQM for the reporting of any CAPA non-conformities • Liaise with relevant research teams to ensure the procedure outlined above is followed, recorded and completed • Escalate any concerns to the senior management team
Research team	• Liaise with QA team to ensure timely and effective completion of the process as outlined above • Ensure all preventative actions are incorporated into practise
Senior Management	• Liaise with QA team to maintain programs of audit and monitoring • Attend QA meetings to ensure QA departmental oversight • Work with the QA team to address any findings escalated to senior management and report to RDD as necessary