**Summary of QMS Deficiencies in 2024**

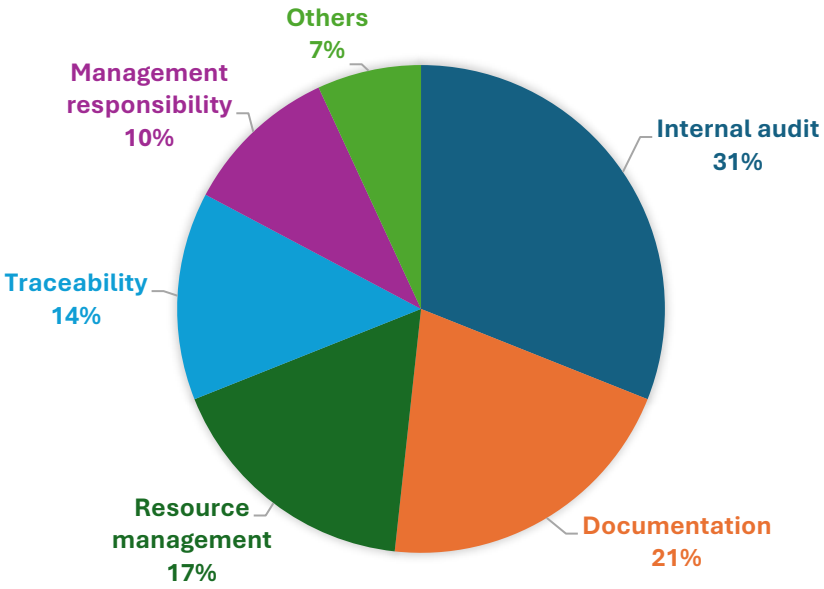



**Figure 1: Areas of deficiency found during GDPMDS audits conducted by ACBs in 2024.**

Note: SAC accreditation for ISO13485 certification was implemented in January 2025

**Table 1: Examples of deficiencies**

| Clause | Examples |
|---|---|
| Documentation | - Site Master File was not effectively maintained (e.g. edition number and effective date not present)<br>- Record control process was not adequately maintained for records providing traceability of medical devices delivered to end user |
| Management responsibility | - There was no evidence of planning and conduct of management review in the last 12 months.<br>- Management review process was not effectively implemented as per SOP |
| Resource management | - No training records pertaining to QMS of staff |
| Traceability | - Records providing traceability of medical devices from the supplier and to the customers was not maintained (e.g. batch number or serial number not found in the delivery document from supplier) |
| Internal audit | - Internal audit not conducted on a regular basis |

To request for a QMS/regulatory audit summary or excerpt, submit a request here.