Summary of QMS Deficiencies in 2025

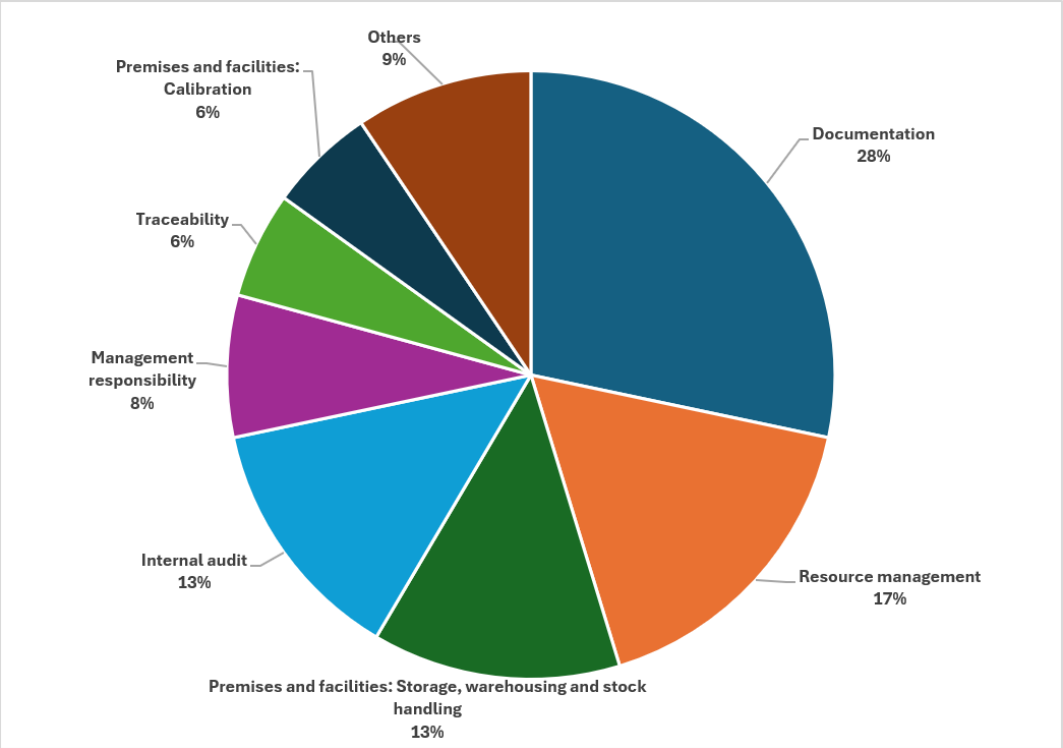


Figure 1: Areas of deficiency found during GDPMDS audits conducted by ACBs in 2025.

Table 1: Examples of GDPMDS deficiencies

Clause	Examples
Documentation	• Incomplete or Outdated Documentation and Quality System Records • Gaps Between Documented Procedures and Actual Operations
Resource management	• Inadequate Training Records and Competency Documentation • Gaps in Staff Training on Regulatory Updates and Standards • Lack of Training Effectiveness Evaluation
Premises and facilities: Storage, warehousing and stock handling	• Incomplete Implementation of Pest Control Programmes and insufficient record-keeping and monitoring • Inadequate Cold Chain Storage Controls and Hygiene Practices
Internal audit	• Incomplete Management Review Agenda and Process • Inadequate Internal Audit Planning and Scheduling

	• Gaps in Internal Auditor Qualification and Conduct
Management responsibility	• Inadequate or Absent Management Review Process • Poor Sequencing of Internal Audit and Management Review Activities • Insufficient Management Representative Awareness of Regulatory Guidance

Figure 2: Areas of deficiency found during ISO13485 audits conducted by ACBs in 2025.

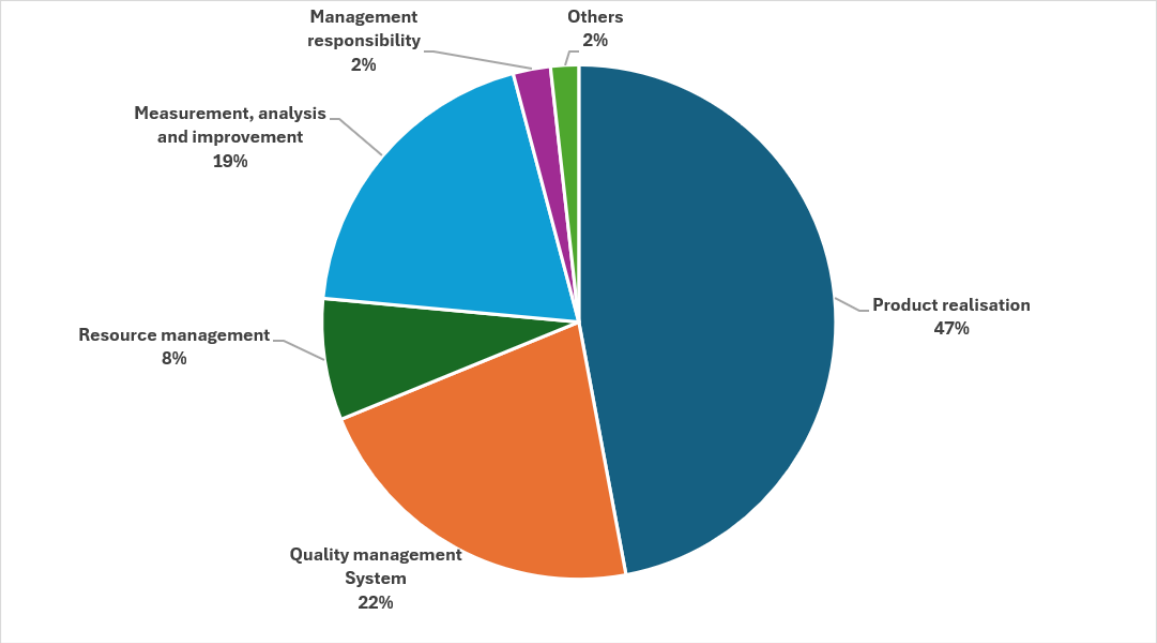


Table 2: Examples of ISO13485 deficiencies

Clause	Examples
Product realisation	• **Incomplete Risk Management and Design Control Processes** — Risks were not adequately identified, analysed, and documented across the design and development process. • **Inadequate Supplier Evaluation, Incoming Inspection, and Traceability Controls** — Suppliers were not consistently re-evaluated, inspections were missed, and traceability records were incomplete. • **Gaps in Process Validation, Final Inspection, and Production Record-Keeping**

	— Validation lacked defined parameters, final inspection criteria were absent, and production records were insufficient.
Quality management system	• **Incomplete Risk Management Documentation and Implementation —** Risk management plans, benefit-risk analyses, and residual risk evaluations were absent or incomplete. • **Gaps in Supplier Control and Outsourced Process Management —** Quality agreements with critical suppliers were missing and outsourced processes were not adequately identified or controlled. • **Inadequate Document Control and Retention Requirements —** Documents lacked revision status, retention periods were non-compliant, and applicable regulatory requirements were not updated.
Measurement, analysis and improvement	• **Ineffective Feedback, Complaint Handling, and Post-Production Data Analysis** — Post-production data and complaint findings were not fed back into risk management or quality improvement processes. • **Incomplete Internal Audit Scope, Planning, and Auditor Competency** — Audit schedules excluded applicable clauses, records were missing, and auditor competency could not be verified. • **Gaps in Process Validation, Change Control, and Corrective Action Effectiveness** — Process validations were incomplete, changes were not validated prior to implementation, and corrective action effectiveness was not verified.
Resource management	• **Inadequate Training Records and Demonstration of Staff Competency** — Training sessions were conducted but records were not updated, and operator competency could not be demonstrated. • **Insufficient ISO 13485 Awareness amongst staff**

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