

## **Introduction**

Authoring Engineer – Medical Devices (MD)

## **Purpose**

The AE (MD) is an expert in Managing Medical Devices who can audit healthcare organisations against the Medicines and Healthcare products Regulatory Agency (MHRA) requirements - Managing Medical Devices - Guidance for health and social care organisations.

The AE (MD) must talk to key stakeholders, review evidence, determine the compliance levels, then report / advise on improvements to reduce risks and improve patient safety.

The AE (MD) will use their expert knowledge to review policies, governance and performance then complete a management report for the organisation with recommendations for improvement.

ID	AE (MD) Prompts from MHRA guidance
1	Healthcare organisations should appoint a director or board member with overall responsibility for medical device management
2	Healthcare organisations should establish a medical devices management group to develop and implement policies across the organisation.
3	A device management policy should help to ensure that risks associated with the use of medical devices are minimised or eliminated.
4	Good record keeping is essential for the safe management of medical devices.
5	Systems for managing medical devices need to take account of the different ways that the devices can be deployed.
6	Monitoring the organisation's performance on medical device management is important to minimise or eliminate risks to patients and staff.
7	Reporting adverse incidents
8	Every healthcare organisation should ensure there is a policy or other mechanism for the acquisition and selection of appropriate devices for specific procedures.
9	Factors to consider before acquisition.
10	Modifying and changing use: Modifying existing devices or using them for purposes not intended by the manufacturer (off-label use) has safety implications.
11	Rationalising the range of models versus diversity
12	Buying maintenance support services
13	Healthcare organisations should check that the specification of newly delivered devices matches the purchase order detail or tender specification.
14	All devices on loan from manufacturers should be subject to a written agreement.
15	Healthcare professionals working for the organisation, as employees or contractors, have a professional duty to ensure their own skills and training remain up to date.
16	A training policy should be developed by the medical devices management group.
17	Evidence that suitable instructions and training were provided are needed.
18	Good clear instructions for use have a crucial role in the safe and effective use of devices.

19	Evidence that suitable instructions and training were provided.
20	The healthcare organisation's medical device management policy must cover the provision of maintenance and repair of all medical devices.
21	Choosing appropriate maintenance and repair services.
22	Service Contracts: Any contractual agreement with a maintenance and / or repair service provider should specify the level and type of service required.
23	Training and experience of repair and maintenance staff
24	Spare parts and other components - quality and availability.
25	Repair and maintenance methods.
26	Healthcare organisations should keep patients, staff and visitors safe and have policies and systems in place to ensure that all reusable medical devices are properly decontaminated prior to use or maintenance.
27	Decommissioning and disposal of devices.
28	Compliance with legislation that applies to the organisation