

GMDN Agency – Quality Policy

Policy Statement

We are committed to comply with the requirements the quality management system and continually improve its effectiveness. We are also committed to establishing and reviewing our quality objectives.

Scope of Quality Management System

The GMDN Agency provides health authorities, regulators, health care providers, medical device manufacturers, suppliers, and conformity assessment bodies with a generic naming system for all medical devices.

Strategic Aims

- Assist in the protection of patients by acting as a resource for healthcare regulators to help them identify trends and solve problems quickly
- Facilitate collaborative efforts between regulators in different jurisdictions
- Support regulators in the adoption and implementation of the GMDN to support their regulatory efforts (e.g., UDI-DI implementation)
- Support regulators and industry in the setting up of registries and learning communities
- Support users to reduce the risk of misuse or misassignment of GMDN terms by taking the lead on the quality of Terms assignment, to ensure they are as accurate as possible for downstream use
- Assisting stakeholders in the downstream use of GMDN Database as a leveraging interoperability tool e.g., inventory/asset management, real world evidence analysis, signal detection
- Offer expertise and insight to the whole medical device supply chain
- Demonstrate the advantages of greater global harmonisation and medical technology for patient care
- Increase transparency of the Agency through stakeholder engagement and communication of activities

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