

QUALITY MANAGEMENT SYSTEMS (QMS) ACRONYMS

Acronym	Meaning
CAPA	Corrective and Preventive Actions
DHF	Design History File
DHR	Device History Record
DMR	Device Master Record
eQMS	Electronic Quality Management System
FDA	Food and Drug Administration
IVDR	In Vitro Diagnostic Regulation
ISO 13485	International Standard for Quality Management Systems for Medical Devices
ISO 9001	International Standard for Quality Management Systems (general)
MDR	Medical Device Regulation
MDSAP	Medical Device Single Audit Program
OFIs	Opportunities for Improvement
PMCF	Post-Market Clinical Follow-Up
PSURs	Periodic Safety Update Reports
QMR	Quality Management Representative
QMS	Quality Management System
QMSR	Quality Management System Regulation
SaMD	Software as a Medical Device
SOPs	Standard Operating Procedures