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STANDARDS & GUIDANCE BRIEF · INTERNATIONAL · REGULATORY AUDIT PROGRAM

MDSAP

Medical Device Single Audit Program

DOCUMENT	QES-WP-114, Rev B	DATE	November 7, 2026
ISSUED BY	Regulators of Australia, Brazil, Canada, Japan, and the United States	PREPARED BY	Conner Davidson
EDITION	Program in operation (audit model based on ISO 13485:2016 plus each country's requirements)	STATUS CHECKED	October 24, 2026
INDUSTRIES	Medical Devices	ONLINE	qesisbest.com/standard-mdsap.html

CURRENT EDITION Five participating authorities — Australia's TGA, Brazil's ANVISA, Health Canada, Japan's MHLW and PMDA, and the US FDA — with the EU, Singapore's HSA, the UK MHRA and WHO prequalification as observers, and further affiliate members.

What It Covers

One audit of a device manufacturer's quality system, by a recognized auditing organization, that each participating regulator can use in place of, or alongside, its own inspection.

Who It Applies To

Manufacturers selling into two or more participating markets. Health Canada requires MDSAP certification for device licensing.

Key Requirements

- An audit against ISO 13485:2016 plus the requirements of each participating jurisdiction you sell into.
- A three-year cycle: initial certification audit, annual surveillance audits, recertification.
- Findings graded on the MDSAP scale, with reporting deadlines for remediation.
- FDA accepts MDSAP audit reports as a substitute for routine inspections.

What an Auditor Asks to See

- Evidence of each country's requirements — registration, reporting, labeling — not only ISO 13485.
- Responses to graded nonconformities within the program's deadlines.

Where Systems Fall Short

- Country-specific requirements missing for a market added since the last audit.
- Nonconformity responses late or without evidence.

How QES helps. A mock audit run on the MDSAP model, country requirements included. See the mock certification audit: qesisbest.com/services.html#mock-audit · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. TÜV SÜD — Medical Device Single Audit Program — www.tuvsud.com/en-us/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification/medical-device-single-audit-program-mdsap.

A summary for orientation, prepared by Quality Excellence Services. It does not reproduce or replace the standard or regulation: read the official text, which governs. Not legal advice.