WHAT YOU NEED TO KNOW ABOUT MDSAP

Which countries and regulators are involved? Which regulations are applicable?





TGA	Health Canada	MHLW	FDA	ANVISA
TG(MD)R Sch 3	SOR/98-282	Ordinance 169	21 CFR Part 820	RDC 16/2013

What is the audit approach and the scope of the audit?

The regulatory approach is ISO 13485 + requirements of the five countries. Instead of multiple audits and inspections, one MDSAP audit will cover all Quality Management System requirements. Saving time and money.

The audit covers:


Management


Analysis Improvement


Design and Development


Marketing and Facility Authorization


Measurement


Production and Service Controls


Purchasing


Adverse Events and Advisory Notice Reporting

Which sites require their own audit?

Each site involved in the product life cycle. For example...

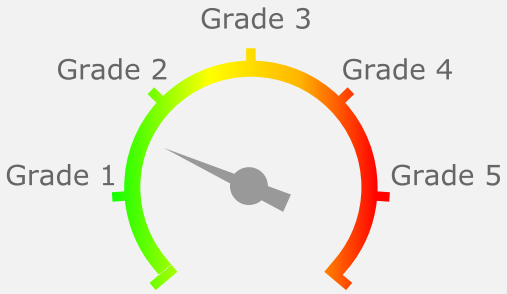

Medical device designer


Manufacturer


Distributor

. . .

How does MDSAP grade non-conformities?



- The higher is the risk associated with non-conformity, the higher is the grade of the nonconformity.
- Lack of procedure the failure resulting in placing noncomliant products on the market adds 1 point to the non-conformity grade.
- One grade 5 or two grade 4 non-conformities trigger additional requirements for the follow-up

What does the MDSAP audit process look like?

Initial Audit
A complete audit of a medical device manufacturer's Quality Management System

→ **Surveillance Audit** Year 1

→ **Surveillance Audit** Year 2

→ **Recertification Audit** Year 3

Should MDSAP-conform medical devices be approved in each separate country?

Yes. Before medical devices are marketed, specific approval on a country-by-country basis is still required.