

QMS FRAMEWORK APPLICABILITY CHECKLIST

A quick screen for ISO 13485, FDA QMSR, MDSAP and ISO 9001

1. YOUR ORGANIZATION'S ROLE

- We are the legal manufacturer or specification developer.
- We design, manufacture, package, label, sterilize or service devices.
- We supply components, software or services to medical device organizations.
- We operate in both medical device and non-medical sectors.

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2. PRODUCTS AND ACTIVITIES

- We control device design, production, release or change decisions.
- We outsource manufacturing, sterilization, testing or software development.
- We manage complaints, servicing or post-market information.
- Our activities require validation, traceability or special process controls.

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3. TARGET MARKETS

- We market or plan to market medical devices in the United States.
- We target Canada, Australia, Brazil or Japan.
- We also target the European Union, United Kingdom or other regulated markets.
- We need one QMS to address multiple country-specific controls.

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4. AUDIT AND CERTIFICATION SIGNALS

- We need or are considering ISO 13485 certification.
- Our U.S. activities may fall within FDA QMSR scope.
- We need or are considering an MDSAP audit.
- ISO 9001 applies to our wider business or customer requirements.

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INITIAL FRAMEWORK SNAPSHOT

ISO 13485

Medical device lifecycle

FDA QMSR

U.S. regulated activities

MDSAP

Participating authority markets

ISO 9001

Wider business QMS

Initial screening only. Applicability depends on role, activities, products, sites, markets and regulatory requirements.