MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP)

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WHAT IS IT?

It is an international program promoted by the **International Medical Device Regulators Forum (IMDRF)**

Which allows **a single audit** of a medical device manufacturer's quality management system **to be accepted by multiple regulatory authorities**

WHAT IT CONSISTS OF

Verification of compliance with the local regulatory requirements of each participating country

Review of technical documentation and product traceability

Audit of the quality management system

Evaluation of design, production, distribution, and post-market surveillance

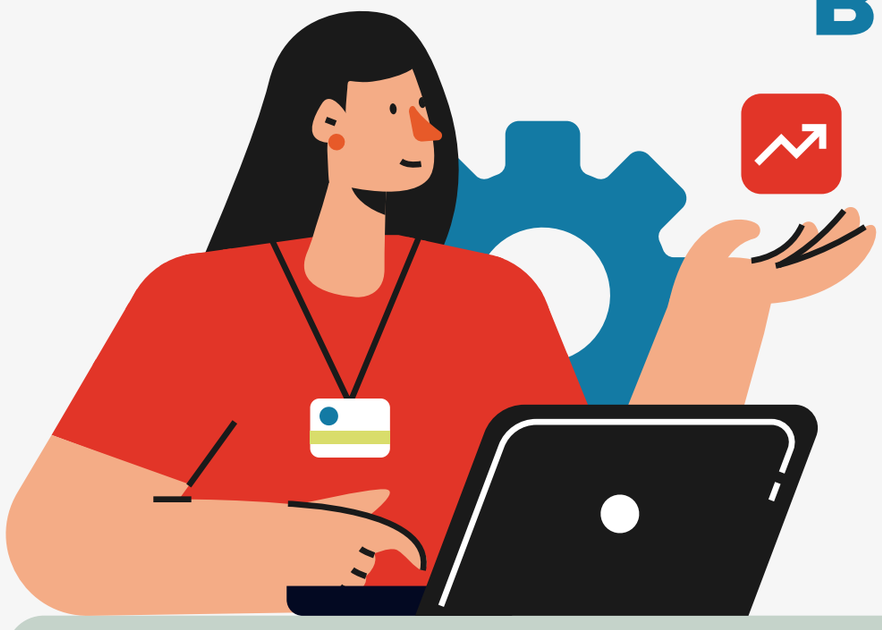
CHARACTERISTICS

- Based on the ISO 13485 Standard
- Based on a process-oriented audit model
- Harmonizes regulatory requirements among countries
- In-depth and standardized audit
- Annual or surveillance audits based on risk

WHO CAN IMPLEMENT IT

- Manufacturers
- Importers
- Distributors
- Healthcare organizations

BENEFITS



A single audit for multiple approvals

Increased operational efficiency

Enhanced quality and traceability

Reduction of redundancy and costs

More agile access to global markets

Improved international compliance

References: *FDA. Medical Device Single Audit Program (MDSAP).* Viewed online at: Medical Device Single Audit Program (MDSAP) | FDA on 30/04/2025

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