MDSAP Audit Approach

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Background

Medical Device Manufacturer…

…desires to provide medical devices to many countries

… is committed to meeting the regulatory requirements of the country's Health Authority

…focuses on the patient / customer

Without programs like MDSAP…

…medical device manufacturer experiences an increase in audit demands when distributing to large number of countries

…individual country requirements lead to different audit approaches

…audits are resource intensive for both the health authority and the medical device manufacturer

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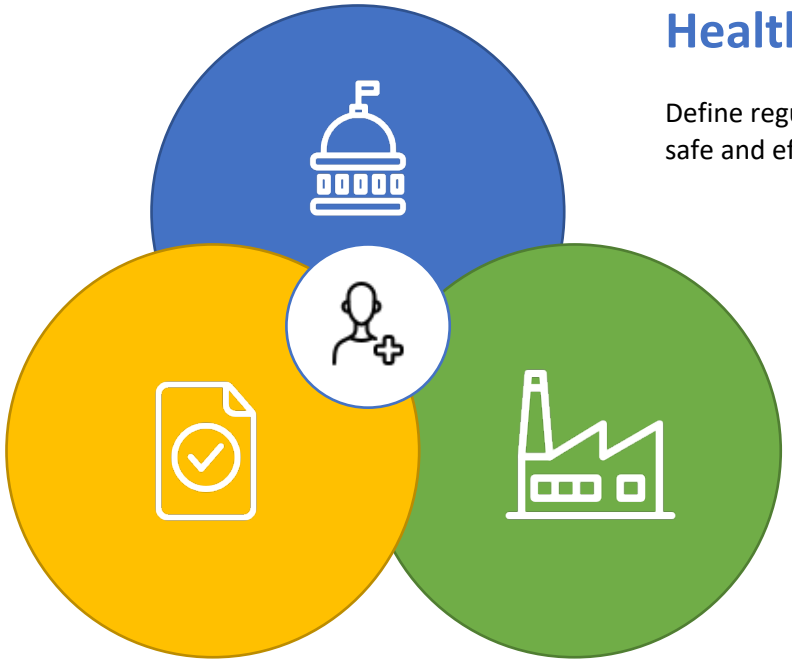
MDSAP Audit Approach - Roles

Notified Body (Auditing Organization)

Authorized, independent review of the manufacturer's compliance to Health Authority's requirements.
Audit reports and certificates shared with participating Health Authorities.



Health Authority

Define regulatory requirements to protect the public, ensuring safe and effective medical devices are placed into the market.

Medical Device Manufacturer

Implements regulatory requirements, maintaining a quality management system that ensures the production, delivery of safe and effective medical devices.

MDSAP Approach - Positives

Single Audit – Multiple Regulatory Authorities

- ISO13485:2016, Australia, Japan, Brazil, Canada, and USA

Structured, prescribed process of defined tasks

Results in ...

- ↓ need for duplicate audits
- ↓ resources for regulatory authority
- ↓ resources for medical device manufacturer

Question & Answers

THANK YOU

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