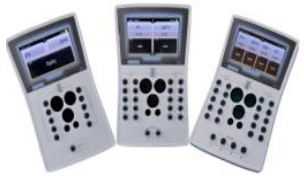
A clear view into the future !

MDSAP

Harmonisierung von Auditprozessen: Chancen und Herausforderungen

Lara Alina Schöllbauer, MSc, MBA

technoclone



Herstellung von diagnostischen Tests und Equipment zur Blutgerinnungsdiagnostik

Standort: Wien

Unternehmensgröße: KMU

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MDSAP

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Scope

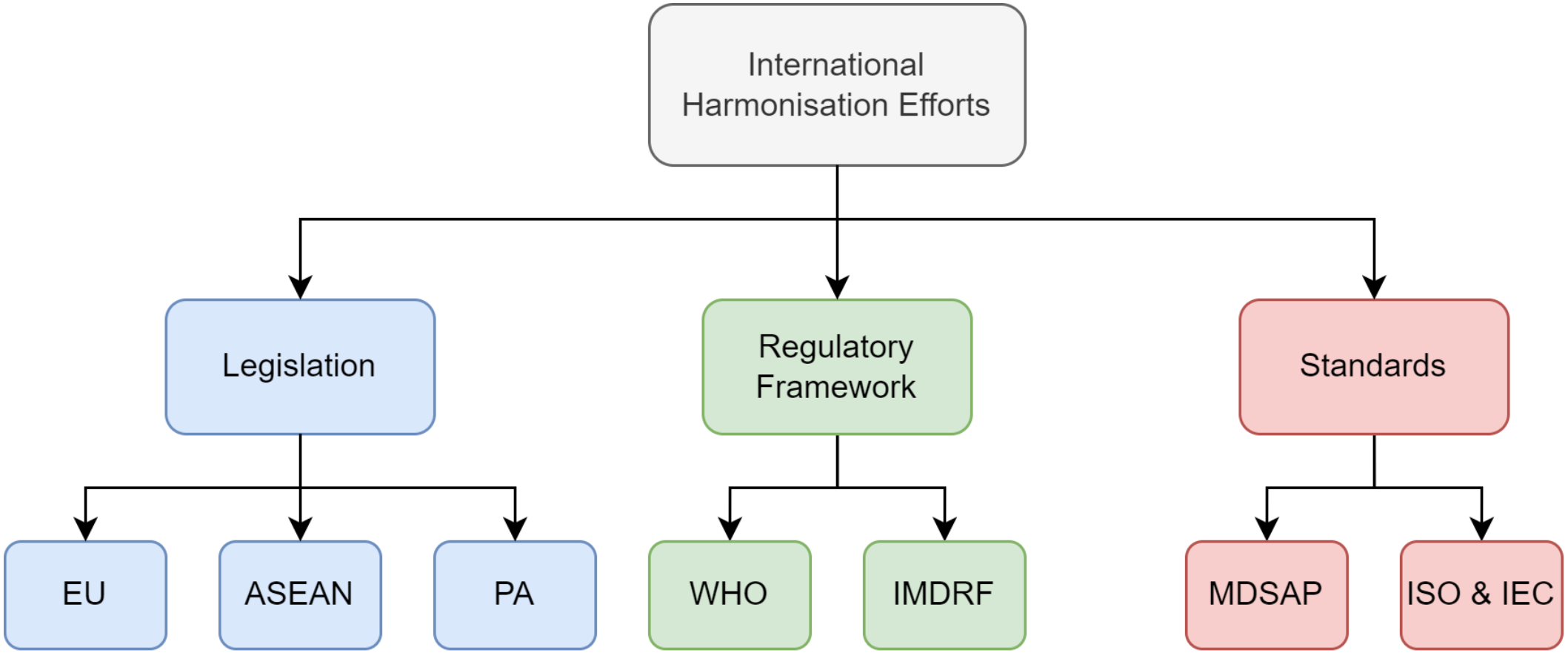
Auditorganisation

Projektteam

Umsetzung

Chancen & Herausforderungen

MDSAP – Harmonisierung von Auditprozessen



MDSAP – Medical Device Single Audit Program

IMDRF International Medical Device Regulators Forum

What are you looking for?

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Closed working groups

Medical Device Clinical Evaluation

Improve the effectiveness and efficiency of the pre-market review process by promoting increased global harmonization.

Medical Device Cybersecurity Guide

Manage cybersecurity risks in medical devices through a life-cycle approach. Striking the right balance between pre-market and post-market requirements.

Medical device single audit program (MDSAP)

Leverage regulatory resources to manage an efficient, effective, and sustainable single audit program.

Roadmap for implementation of UDI

Software as a Medical Device (SaMD)

MDSAP – Medical Device Single Audit Program

Medical Device Single Audit Program (MDSAP)

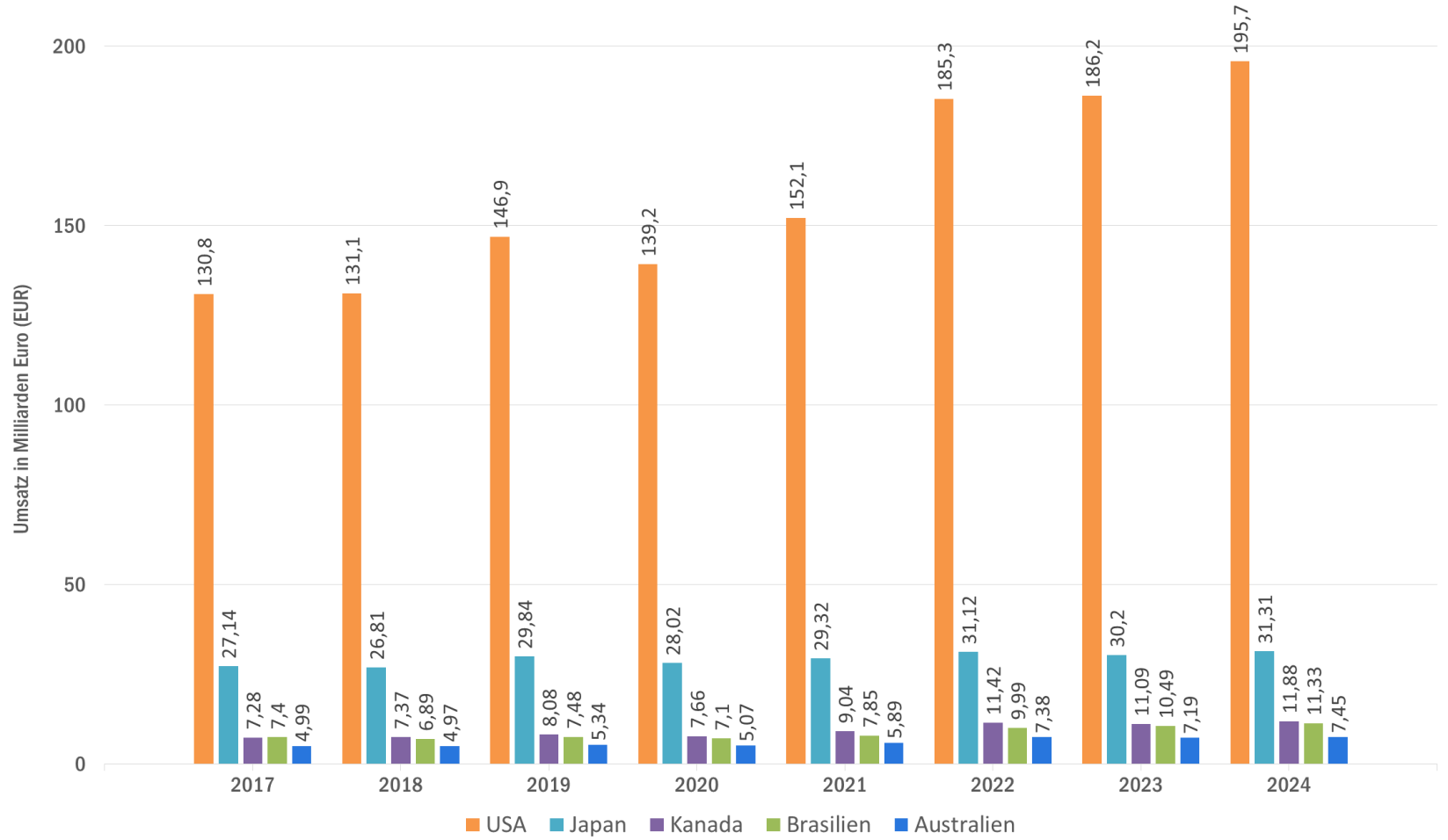
- behördliches Auditprogramm
- Ermöglicht Herstellern von Medizinprodukten ein einziges Qualitätsmanagementsystem-Audit durchzuführen, welches die Anforderungen aller teilnehmender regulatorischen Behörden erfüllt

Jedes Land legt fest, wie die Ergebnisse des MDSAP in seinem Zuständigkeitsbereich in Übereinstimmung mit seiner Gesetzgebung und seinem Rechtsrahmen verwendet werden.

MDSAP – Regulatory Authorities

Australien	Therapeutic Goods Administration (TGA)
Brasilien	Agência Nacional de Vigilância Sanitária (ANVISA)
Kanada	Health Canada (HC)
Japan	Ministry of Health, Labour and Welfare (MHLW) & Pharmaceuticals and Medical Devices Agency (PMDA)
USA	Food and Drug Administration (FDA)

MDSAP – Market Size



MDSAP – Audit Approach

(1) Management

(2) Device Marketing Authorisation & Facility Registration

(3) Measurement, Analysis & Improvement

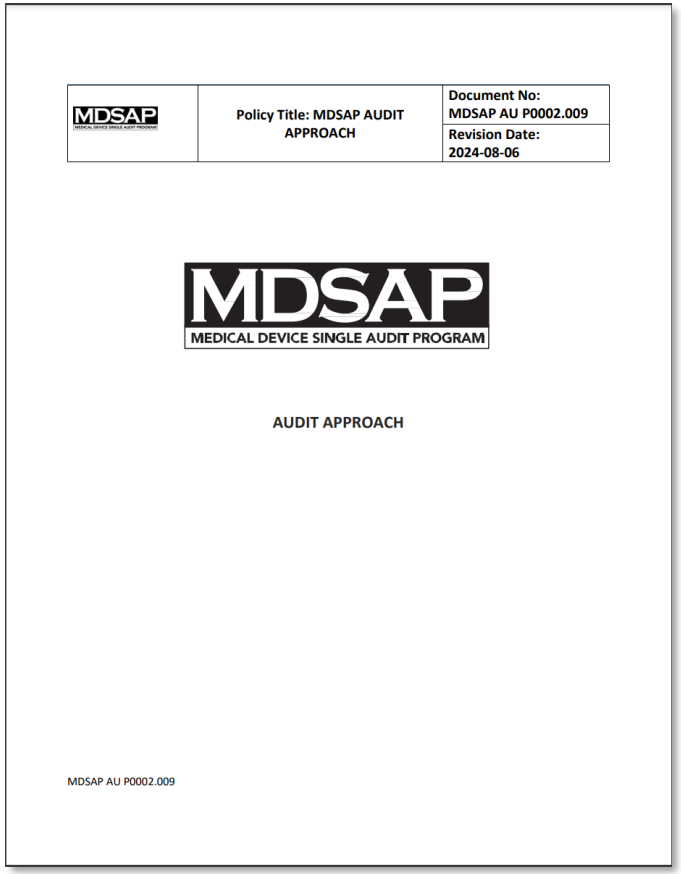
(4) Medical Device Adverse Events &

Advisory Notices Reporting

(5) Design & Development

(6) Production & Service Controls

(7) Purchasing



MDSAP – Auditing Organisations

FDA U.S. FOOD & DRUG ADMINISTRATION

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Auditing Organization Availability to Conduct MDSAP Audits

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Medical Device Single Audit Program (MDSAP)

MDSAP Documents

The organizations listed below submitted an application to the Medical Device Single Audit Program (MDSAP). The table specifies their status regarding their application, their authorization to conduct MDSAP audits, and their recognition.

Content current as of:
05/30/2024

Regulated Product(s)
Medical Devices

Search:

Eligible Auditing Organization	Location	Contact	Application Received	Authorized to Conduct MDSAP Audits	Recognition
bsi.	BSI Group America Inc. 12950 Worldgate Drive, Suite 800, Herndon, VA 20170 USA **Critical Location** Milton Keynes, UK	**Morgan Quandt** Morgan.quandt@bsigroup.com +1 571 443 1708	Yes	Yes	Yes
DEKRA	DEKRA Certification B.V. Meander 1051 Arnhem, 6825 MJ Netherlands **Critical Locations**	**Adriano Mulloni** mdsap.nl@dekra.com +31 88 96 83408	Yes	Yes	Yes

MDSAP – Audit Cycle

Auditzyklus: 3 Jahre

- Initial Audit (Zertifizierungsaudit): vollständiges Audit des QM-Systems
  - Stage 1: Documentation Review – readiness evaluation for stage 2
  - Stage 2: On-site Assessment
- 1st Surveillance Audit
- 2nd Surveillance Audit
- Re-Audit (Rezertifizierungsaudit)

MDSAP – in der Praxis aus Sicht eines KMUs

Betriebswirtschaftliche Überlegungen

- Marktzugang und Expansion
- Scope
- Konkurrenzfähigkeit
- Risikominimierung
- Aufwand und Ressourcen

MDSAP – in der Praxis aus Sicht eines KMUs

Chancen & Herausforderungen

- Auswahl der MDSAP Auditorganisation
- MDSAP Projektteam
- Umsetzung der Anforderungen
- Erkenntnisse aus MDSAP Audits

A clear view into the future !

Herzlichen Dank für Ihre Aufmerksamkeit!

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Your partner in Coagulation !