III Seminário Brasil - Japão
Regulações
Produtos Farmacêuticos e Produtos para Saúde
**Introduction - ABIMO**

**ABIMO** – Brazilian Medical Devices Manufacturers Association

Its represents ours members before governmental and civil bodies, also supporting them with technical and normative services.

**1962**

Foundation with 25 members

**1971**

ABIMO/SINAEMO become official representatives of the sector

**2015**

340 members, divided into six sectors

**66%** of all companies on medical sector are members of ABIMO

**80%** of the sales revenue on medical sector are from members of ABIMO
Introduction – ABIMO – Sub-Sectors

Consumables
- Hypodermic
- Textile
- Adhesives
- Others

Dental products
- Equipment
- Consumables
- Instrumental

Medical Equipments
- Furniture (no electric)
- Electromedical
- Surgical Instruments
- Physiotherapy Equipment
- Hospitality sector

Radiology
- Equipment
- Accessories
- Consumables

Laboratory
- Equipment
- Reagents
- Other consumables

Implants
- Equipment
- Reagents
- Other consumables
Brazilian Health Devices & Apex-Brasil

Brazilian Health Devices project aims to **increase Brazilian exports** in health products by promoting training to companies, marketing actions, exhibitions, trade missions and business intelligence.

- Exports program **started in 2002** with 82 companies
- Currently, 160 companies are affiliated and **90% of them are exporters**
- Brazilian health products **exports have grown by over 260%** since 2002
Brazilian Health Devices & Apex-Brasil
Brazil - Japan Seminar

Local X MDSAP Certification

• low manufacturer participation rates in MDSAP due to cost-benefit among some companies

• slow rates of auditing organization accreditation by some regulators

• Medical Device Regulatory Audit Reports
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MDSAP is NOT a free ride

Auditing organizations will charge a significant premium for these audits to cover their added expense of:

- Certification process
- Paper work
- Specialized & specific IMDRF related reports
- Training and certification of personnel
Will MDSAP result in fewer inspections? Regulators can still conduct their own inspections and may do more follow-up inspections to those done by 3rd Party.

If an AO is de-recognized / disqualified by Regulators, what will happen to the manufacturers who have been audited by that specific AO?

Recognition of local Medical Device Auditing Organizations by Brazil and Japão
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- The program likely will become the new model to follow for most medical device manufacturers selling internationally.
- Significant benefits to having one audit per year with predictable schedule.
- Create an opportunity to make the quality system more robust and efficient.
Thank you!

Joffre Moraes
Regulatory Strategy Manager
+55 11 3285-0155
joffremoraes@abimo.org.br