III Seminário Brasil - Japão

Regulações
Produtos Farmacêuticos e
Produtos para Saúde

ABIMO
Associação Brasileira da Indústria de Artigos e Equipamentos Médicos, Odontológicos, Hospitalares e de Laboratórios

ApexBrasil
AGÊNCIA BRASILEIRA DE PROMOÇÃO DE EXPORTAÇÕES E INVESTIMENTOS

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.

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

Radiology

- Equipment
- Accessories
- Consumables

Dental products

- Equipment
- Consumables
- Instrumental

Laboratory

- Equipment
- Reagents
- Other consumables

Medical Equipments

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

Implants

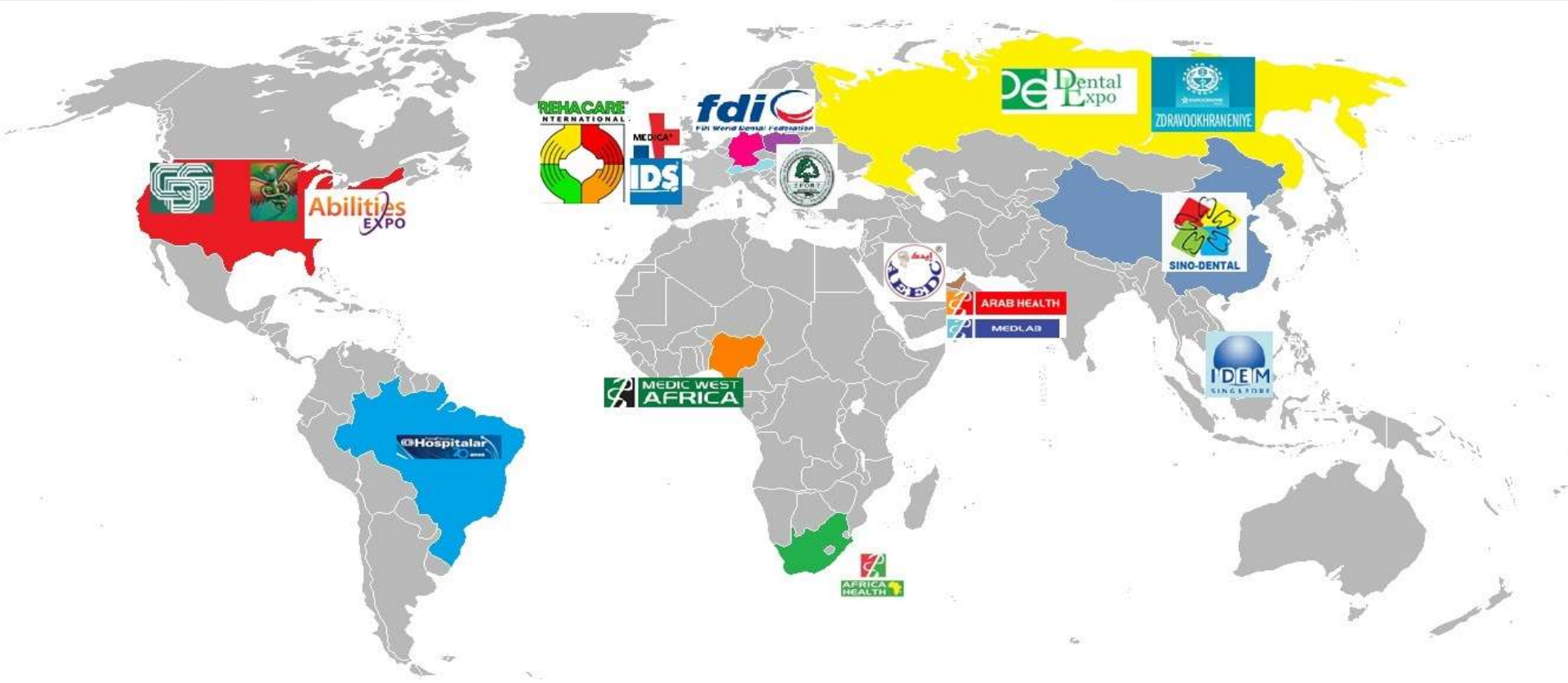
- Equipment
- Reagents
- Other consumables

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

5 Brazilian Health Devices & Apex-Brasil



ABIMO

Brazilian Health Devices

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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

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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

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