



Contribute to Brazilian Medicine with Japanese Medical Devices



**Koji NAKAO, Chairman
The Japan Federation of Medical
Device Associations**

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The Japan Federation of Medical Devices Associations (JFMDA)

➤ 19 Associations

CT/MRI, Intervention, CRM, CV, Neuro, Ophthalmology,
Anesthesia, IV Diagnostics, regenerative medicine and others

➤ 4900 Companies

➤ Sales revenue of ¥ 2,300B ≐ \$23B representing 90% of the industry in Japan

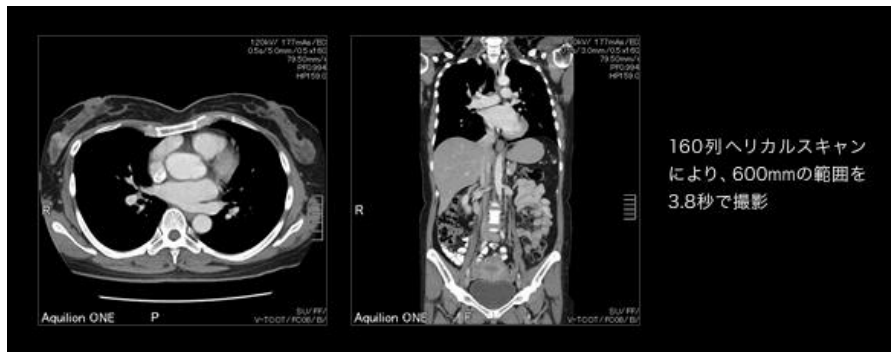
➤ Overseas sales >¥1,300B ≐ \$13B

➤ 120K Jobs

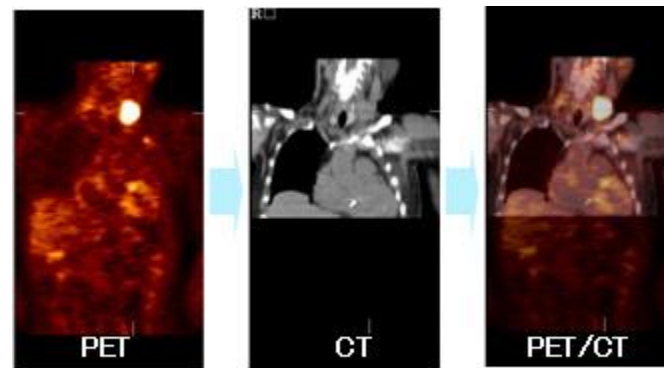
Non Invasive diagnostic imaging

- Early detection of cancer cells and vascular disease with high definition imaging
- Better for patients due to less exposure to radiation

Multi-detector computed tomography



PET CT



肺がん術後(左肺切除)後のリンパ節転移

From the homepage of Toshiba Medical Systems

From the homepage of Shimadzu

Interventional Neuroradiology, Cardiology, Peripheral Radiology

Percutaneous Coronary Intervention

PTCA



Drug Eluting
Stents



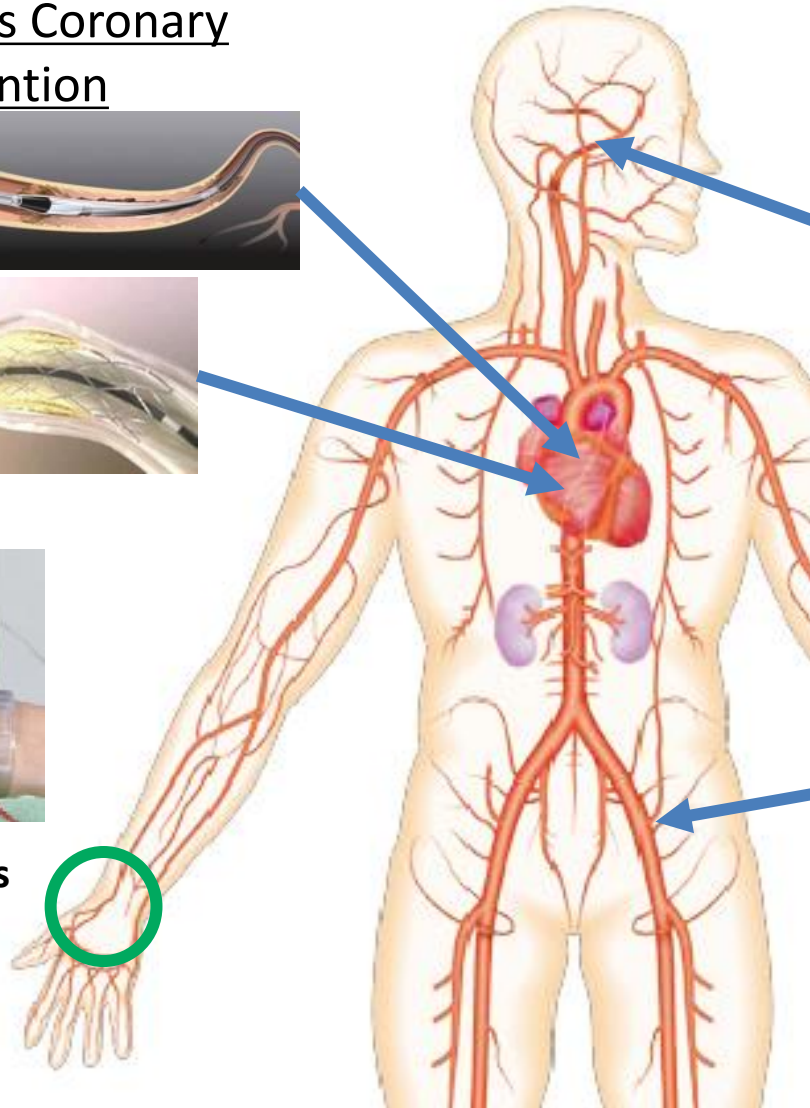
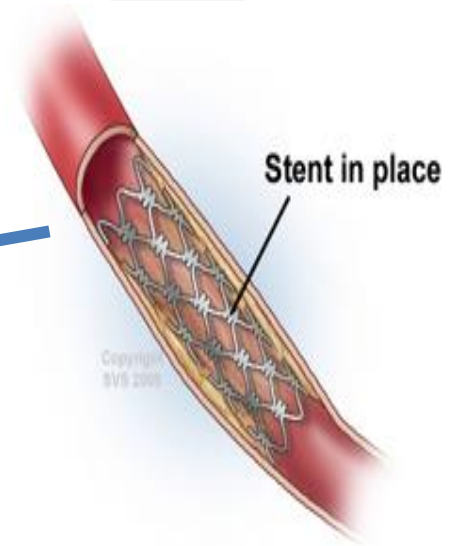
Insertion of catheters
via the radial artery



Neurovascular Embolization Coils



Peripheral Vascular Stents



Investment in Brazil

- **TOSHIBA MEDICAL DO BRASIL LTDA.**
 - New factory opened in 2013. (Sao Paulo).
 - Product: CT and Ultrasonograph

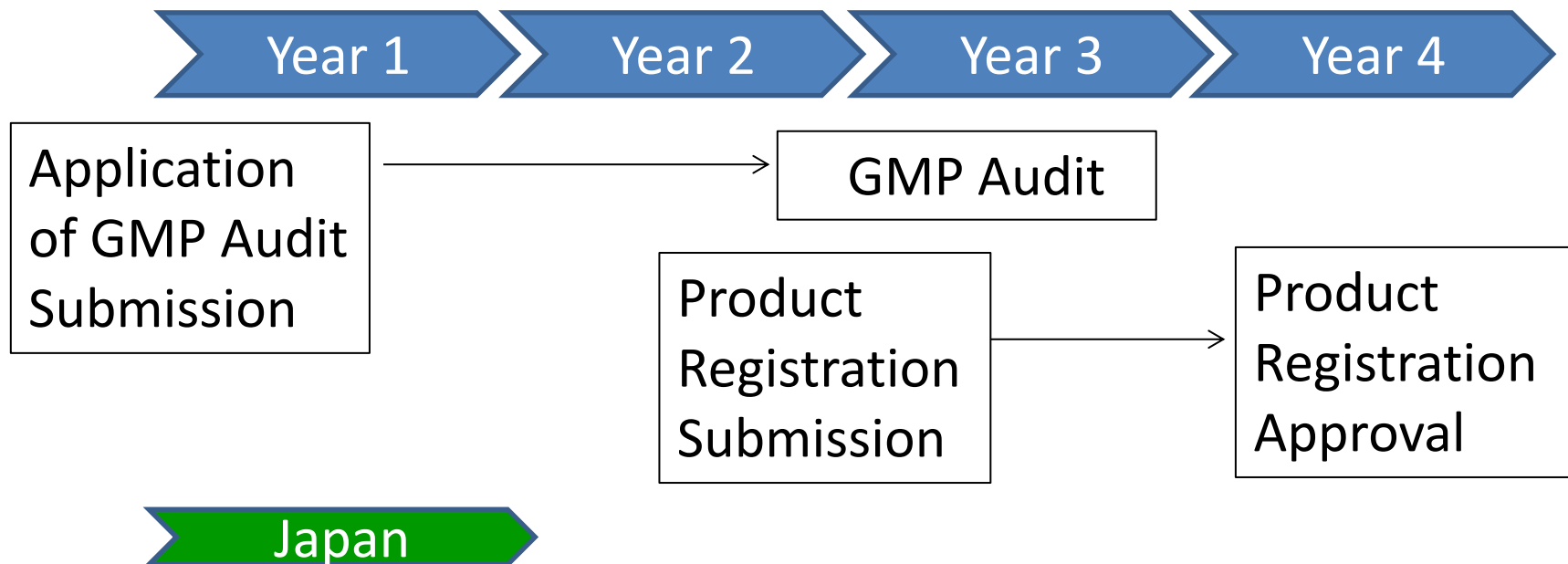
- **HORIBA INSTRUMENTS BRASIL LTDA.**
 - Factory opened in 2014 for reagent production (Sao Paulo) with US\$7M investment.
 - Employee: 70
 - Expected Sales: US\$40M in 2015



Ultrasonograph

Regulatory Issue

- GMP=BPF (Boas Praticas de Fabricacao) audit for the manufacturing sites outside the country
- Product registration for medical devices



Regulatory Issue

Proposals:

- Regular meeting
 - (1) ANVISA and PMDA
 - (2) ANVISA and Medical Device Committee at Câmara de Comércio e Indústria Japonesa do Brasil
- Collaboration with Japanese Stakeholders
 - Visit Japan, and see how Japanese government or PMDA manages regulatory procedures, and also see QMS at medical device manufacturers

| | | Brasil | Japan |
|--------------------------------|---|-------------------------|-------------------------|
| Average life expectancy (yrs) | | 74 | 83 |
| Infant mortality rate (/1,000) | | 13 | 2 |
| Cause of death | 1 | Cardiac disease | Cancer |
| | 2 | Cerebrovascular disease | Cardiac disease |
| | 3 | Cancer | Cerebrovascular disease |

WHO World Health Statistics 2013

**To contribute to healthcare and
people of Brasil**

Thank you