



# REGULATORY CONVERGENCE ON MEDICAL DEVICES – AN INTERNATIONAL TRADE APPROACH



## APEX-BRASIL

The Brazilian Trade and Investment Promotion Agency (Apex-Brasil) is a Civil Society Organization linked to the Ministry of Development, Industry and Foreign Trade.



## MISSION

To develop the competitiveness of Brazilian companies, promoting the internationalization of their businesses and the attraction of Foreign Direct Investment (FDI).

## VISION

Brazil in the World: Innovative, Competitive and Sustainable.

# MAIN ACTIVITIES



## STRATEGIES

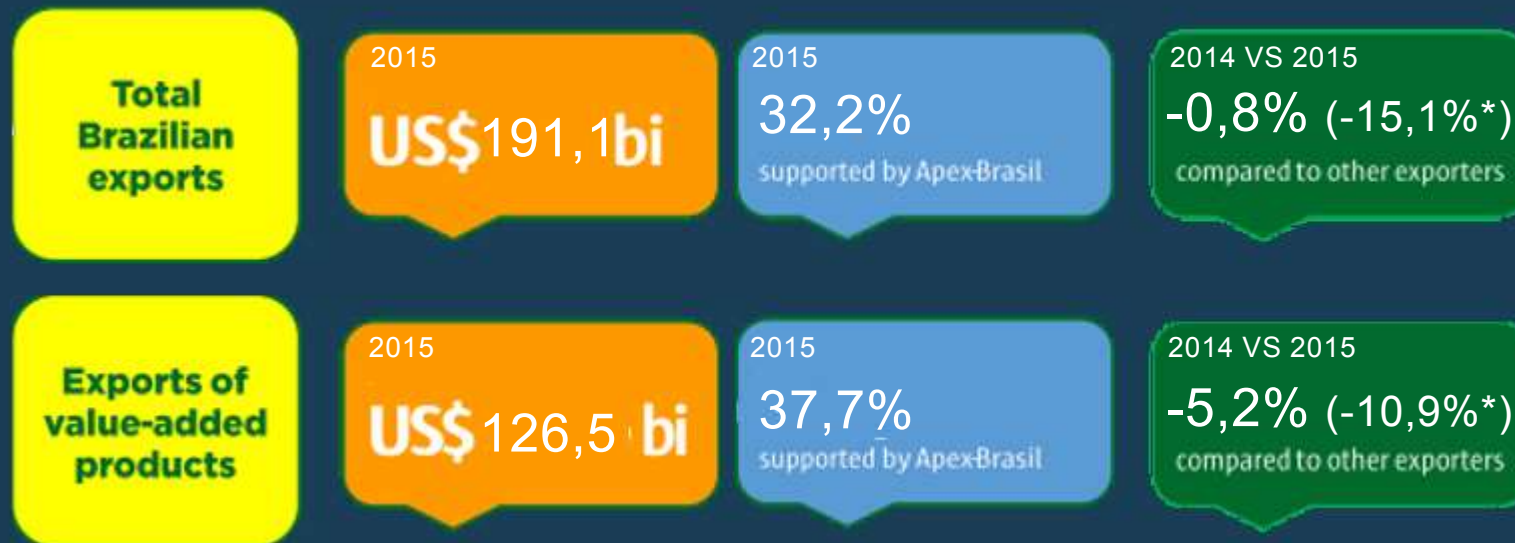
- Market Intelligence
- Entrepreneurial Training
- Internationalization Strategies
- Business and Image Promotion
- Investment Attraction



# 9 OFFICES WORLDWIDE

# APEX-BRASIL EXPORT NUMBERS

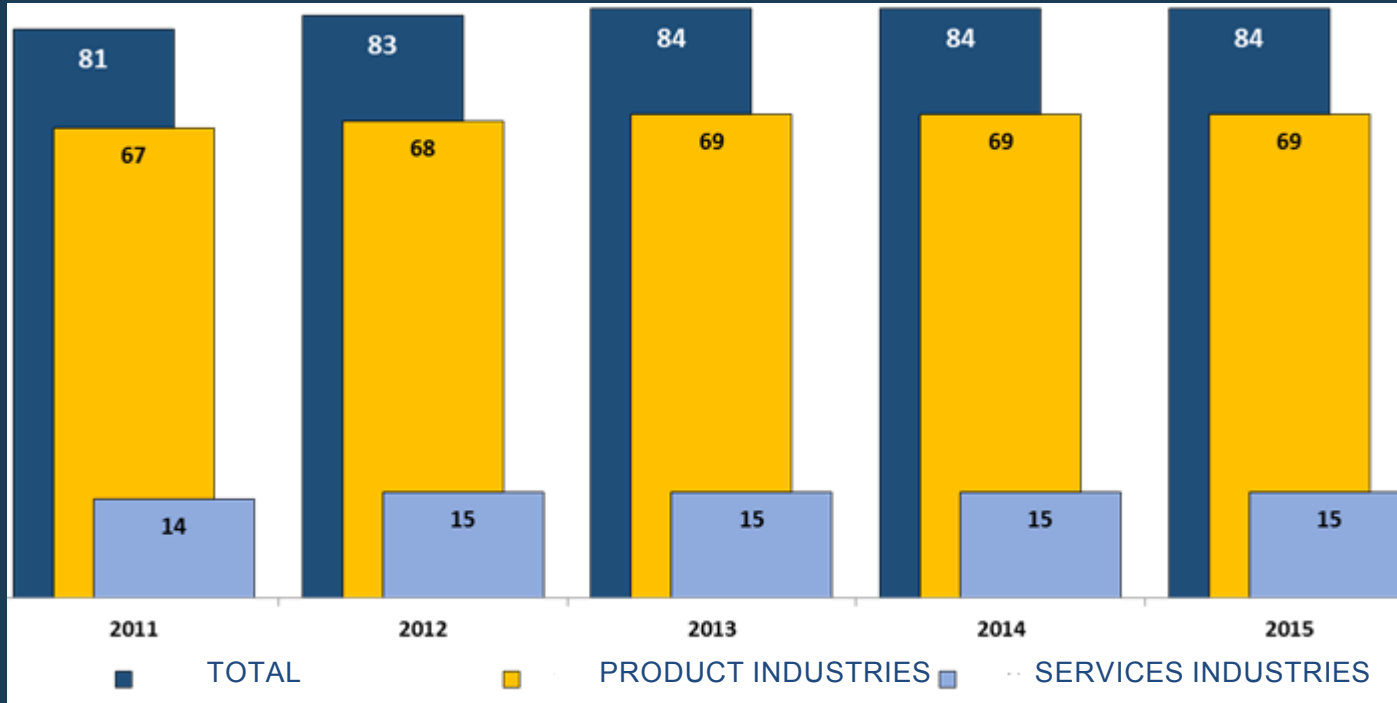
## EXPORT PERFORMANCE BY SUPPORTED COMPANIES



\* OTHER EXPORTERS PERFORMANCE



# SUPPORTED SECTORS



OVER 80

INDUSTRIES SUPPORTED

72 BUSINESS PROJECTS

12.000 SUPPORTED COMPANIES

INITIATIVES TARGETING OVER

200 MARKETS



# TRADE SECTOR PROJECTS



## Definition

We develop and support activities to develop companies' exporting abilities, thus contributing to the promotion of Brazilian industries in the international market. The **Trade Sector Projects** work with business sectors or productive chains, comprising some of Apex-Brasil's main initiatives for stimulating the exports of Brazilian products.

## Goals

The Trade Sector Projects aim to facilitate Brazilian companies' access to the main foreign markets, to prospect business and exporting opportunities, and to improve international perception of Brazilian companies, products and services.

US\$

28,7Bi

Companies supported  
by Trade Sector Projects  
exports

US\$

56,5Bi

Brazilian Exports  
Considering the same services  
and products supported by  
Apex-Brasil

50,9%

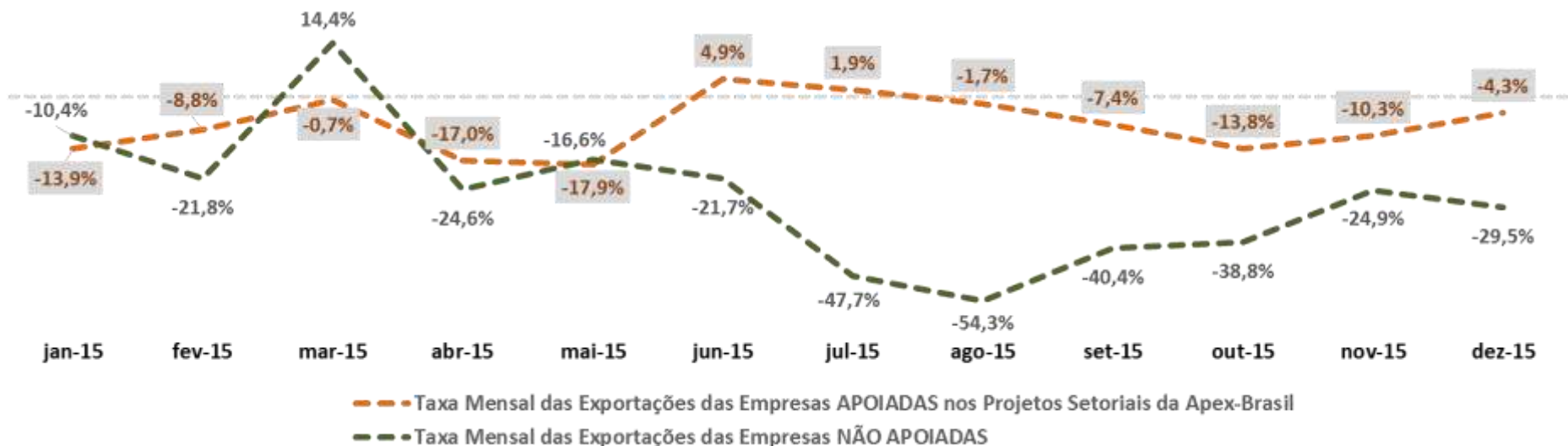
Companies supported  
by Apex-Brasil  
participation

\* From January to December 2014, the  
share was 44,3%

Regarding the Trade Sector  
Projects exports,

The performance of companies  
supported by Apex-Brasil was 74,5%  
higher than by those not supported,

despite the drop in  
export volume  
between January and  
December 2015.







The Sector Project implemented by **ABIMO** (Brazilian Medical Devices Manufacturers Association) **in partnership with Apex-Brasil** is named Brazilian Health Devices and its mission is to **encourage the exports by the brazilian health industry companies.**

## BHD PERFORMANCE IN 2015:

- Companies supported by the project: **157** (125 exporters)
- Supported companies exports: **123.275.021** (US\$ FOB)
- Supported companies exports annual growth: **+ 0,8%** (other exporters had a 10,95% decrease in performance)
- Products (MCNs\*): **117**
- Destinations: **134**

\* MERCOSUR Common Nomenclature





## WHAT THE BRAZILIAN HEALTH DEVICES HAS TO OFFER:

- Business intelligence (information and market analysis);
- Participation in major international trade fairs around the world;
- Organization and promotion of trade missions;
- Business matchmaking rounds in major trade fairs;
- Training for export and international certification;
- Image building;
- Certification Incentive Program;
- Sales Agents in target markets



## HOW IMPORTANT IS INTERNATIONAL CERTIFICATION FOR MEDICAL DEVICES INTERNATIONAL TRADE?

- Health Sector is highly regulated and monitored;
- FDA and CE – stand for quality and security in the international market;
- Growing demand of distributors for FDA e CE certified products;
- FDA e CE – competitiveness requirement for new opportunities

## IMPACT ON COMPETITIVENESS

Brazilian companies spent at least **USD 12,5 thousand** individually to obtain the **CE Mark**; at least **USD 20 thousand** for **FDA**;

**Not to mention all other countries!** For example, for any country in South America, a company might need to spend at least **USD 5 thousand** only in bureaucracy;

China is the country with the most expensive certification (according to statements from BHD companies), with minimum cost of **USD 50 thousand**, without most clinical trials needed.



# STEP-BY-STEP CERTIFICATION INCENTIVE PROGRAM:

1. Introductory meetings and request for proposal;
2. Choose Consulting Partner with best cost x benefit;
3. Kick off Project with BHD companies;
4. BHD companies application to program;
5. Application assessment by Project team (including Consulting Partner);
6. Selection validation by Steering Committee;
7. Signing Program Terms of Participation;
8. Start individual assessment and service by Consulting Partner;
9. Monitoring Program status by BHD team;
10. Pay Consulting Partner in installments, by job completion.

## PROGRAM RESULTS **SO FAR:**

157 BHD companies - **82** have acquired CE certification and **28** FDA certification;

1st edition FDA (2012 – 2013) – 8 companies – ALL OF THEM COMPLETED

2nd edition FDA (2014 – 2016) – 8 companies – 5 COMPLETED AND 3 STILL IN PROCESS

3rd edition CE – 4 companies – IN FINAL STAGE

## PLANS FOR THE **FUTURE:**

**Continue** to invest in certification for BHD companies

In 2016, the Program will have **8 new posts**

Focus on regulatory process for **assistive technologies** sector

**Training on** certification process

Data survey on **regulatory process in 18 target markets**



## FINAL MESSAGE:

1. Regulatory Convergence is an issue of vital importance for the international trade in medical devices. It directly impacts companies competitiveness;
2. From the international trade point of view, initiatives such as the IMDRF can produce a very positive impact;
3. It's essential that the business world and its Stakeholders be in close contact with the health policy decision-making individuals so as to allow foreign trade in the health sector to take place.





# CONTACTS

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