Importance of Synchronized approach on the implementation of the IMDRF recommendations

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IMEDA today
About IMEDA

IMEDA (International Medical Device Manufacturers Association) – A non-profit organization uniting international manufacturers of medical equipment, products, and consumables on the Russian market founded in 2005

IMEDA – common voice of international manufacturers of Medical Devices in RUSSIA

Almost 25% of our members – localized in Russia
IMEDA's Mission

Improving the efficiency of the Health Care System by introducing new technologies and providing the Russian population with modern, high-quality and affordable medical devices

Today the Association unites more than 50 leading international companies operating in the field of high-tech medicine in RUSSIA
The International Medical Device Regulators Forum (IMDRF) – it was established in February 2011 in order to harmonize regulatory requirements for the treatment of medical devices at the international level.

**IMDRF Management Committee** – the Supreme body of the Forum consisting of official representatives of 10 regulatory bodies of the participating countries.

The current members are:
- Australia
- Brazil
- Canada
- China
- Europe
- Japan
- Russia (November, 2013)
- Singapore
- South Korea, and
- the United States of America.
Common achievement

Regulatory Authority + Industry = Open Dialogue

2-3 times per year we have joint meetings

All issues related to circulation of MDs thoroughly discussed

Next steps: some elements of Tech Files/Instruction of Use content for further progress in terms of IMDRF requirements synchronization need to be discussed
IMDRF topics cover all aspects related to the regulation of MDs:

1. Documents submission (Tech Files/Instruction of Use)
2. Registration
3. Labeling
4. Standards
5. Clinical Evaluation
6. Quality Management System
7. Medical Software
8. ..... etc.
The major TASK for Regulatory Authority

To find the **BALANCE**

  *between*

  the Scope of all **SAFETY** requirements for market access

  *vs*

**Market Development** & Affordability of the State of the Art products to patients

Getting this task resolved will for sure

result into the positive development of the market
Risks of an unsynchronized approach

- Different requirements globally
- Excessive pressure on business
- Increase the cost of products
- Delayed product launch/market access
Synchronized implementation of IMDRF recommendations

Less costs for business/HC System/patient

Accelerated product launch to the market

Everyone speaks the same language as a foundation to support and develop a future global single submission format

Outcome: win-win-win situation
Conclusion

✓ Synchronized implementation of the best IMDRF regulatory practices globally will lead to transparent & predictable regulatory environment

✓ Regulatory harmonization across jurisdictions is key to ensure stable supply of save & efficient high-tech products to the market
THE VOICE OF INTERNATIONAL MEDICAL DEVICE INDUSTRY IN RUSSIA

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