Importance of Synchronized approach on the implementation of the IMDRF recommendations

Moscow, March 2019

IMEDA
International Medical Device Manufacturers Association

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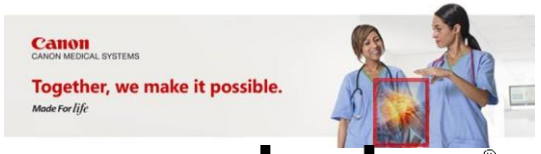
Reckitt Benckiser
Abbott
Johnson & Johnson
ZIMMER BIOMET
Your progress. Our promise.
PHILIPS
sysmex
VALEANT
FRESENIUS MEDICAL CARE
URSAPHARM
BARD
BD
KAVO Kerr
OLYMPUS
Your Vision. Our Future
Boston Scientific
Advancing science for life™
Medtronic
3M
Roche


SIEMENS Healthineers
HARTMANN
Dräger
TERUMO
stryker
smith&nephew
Roche
MERZ
GE Healthcare
ASCENSIA Diabetes Care
BAYER
SCA Care of Life
BIO-RAD
MERIT MEDICAL
FUJIFILM
BIOTRONIK
Edwards
ООО «БЕЛЛА Восток»
seni
matopat
MÖLNLYCKE HEALTH CARE
BECKMAN COULTER
We're better togeth
BIOMÉRIEUX
PIONEERING DIAGNOSTICS
Arthrex
OMRON
Cepheid
A better way.
Alcon A Novartis Division
INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS
FRESENIUS KABI
SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY
Baxter
Ortho Clinical Diagnostics
Allergan
straumann
ConvaTec
Alvogen

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

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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

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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

imeda@imeda.ru
www.imeda.ru

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