INTERNATIONAL CERTIFICATION OF MEDICAL PRODUCTS: A VIEW OF A RUSSIAN MANUFACTURER
International Association of Designers, Manufacturers and Users of Medical Equipment

Established in 1991
63 leading producers of Russia, Belorussia, Bulgaria, Macedonia
more than 8000 types of medical devices produced

Goal: Consolidation of scientific and industrial efforts to support medical industry
JSC «PA «UOMP» is a Major Russian Manufacturer of Medical Equipment

JSC «Ural Optical and Mechanical Plant named after E.S.Yalamov»

Parent company: Holding «Shvabe» of Rostec State Corporation
Location: Russia, Ekaterinburg
Employees: 2 586

Quality management system
ISO 9001-2015,
GOST PB 0015-002-2012,
EN 9100:2016
Products are certified with
EN ISO 13485-2016,
93/42/EEC

Russian Government Quality Award - 2018

10 sales affiliates in Russia

3 overseas subsidiaries.

Shvabe – Zurich GmbH sales affiliate, an OBL-manufacturer (Own Brand Labelling).
The equipment supplied to 47 countries worldwide
Overview of the Russian Medical Industry

- Developing market - **CAGR rate 5.5% for 2013-2025**
- Ongoing national projects and federal programs of health care support
- **€ 23 bln** - total amount of Government funding by a National Project “Healthcare”
- Government support of international industrial cooperation and preferences to localized products subject to correspond the criteria of a national product
- Craving for larger exports

International Industrial Cooperation

Instead of net imports

Joint development & production of medical devices in Russia
Positive Practice of Harmonization with EU Requirements

Russian-based clinical tests verification abroad

Technical and clinical evaluation held in Russia are valid abroad (excl. CIS countries) when Russian company applies for CE/FDA Certificates

No need of equipment supply and repeating tests

JSC “PA “UOMP” Treaton Electronic Systems
Positive experience

Indonesia
Sri Lanka
Vietnam
Philippines
Pakistan
Qatar
Turkey
Ethiopia
Suggestions for further harmonization

**Common regulatory area within the EAEU**
(Russia, Belorussia, Kazakhstan, Armenia, Kyrgyzstan area)

- Unified standards and requirements of QM (e.g. Unified QMS)
- Common EAEU system of technical files verification for medical devices
  (Mutual recognition of the clinical evaluation and laboratory tests)

**Mutual verification of the EAEU and European QM certificates**
WE ARE OPEN TO COOPERATION

THANK YOU!