



REGULATORY AND CUSTOMS SUPPORT

50,000 SHIPMENTS PER MONTH

THE LEADER IN BIOLOGICAL SHIPMENTS IN RUSSIA

Experienced teams throughout our GDP-certified network ensure the safety of your biological and tissue samples

GROWTH

- ✓ The world's largest nation
- ✓ Population: 142,423,773 (July 2015 est.)
- ✓ Ranked 11th in market size, globally
- ✓ Expected to move to 8th by 2017
- ✓ One of the fastest growing in the world, with an annual growth of >10%
- ✓ Market turnover in 2013 was 1,045 billion rubles (17.4 billion USD), and the commercial segment increased by 13.5%
- ✓ In 2014, this value had increased to 1,174 rubles (18.3 billion USD) in final consumption
- ✓ While the production of drugs domestically continues to increase, ~75% of the monetary value of the drugs used are produced abroad

FUTURE

- ✓ Commitment of \$4.8 billion USD (177 billion rubles) to clinical trials and related research
- ✓ Goals include:
 - ✓ Making 60% of local medicines innovative
 - ✓ Local production of pharmaceuticals to be >50% of local consumption
 - ✓ Local production to provide 90% of essential drugs by 2020
- ✓ Clusters have been developed as groups of geographically localized, interconnected, innovative drug-development and drug-producing companies that work closely with universities
- ✓ Five clusters in Yaroslavl, Kaluga, Saint Petersburg, Yekaterinburg and Moscow

REGULATORY

- ✓ Medications cannot be registered without at least a Phase III clinical trial conducted in Russia
- ✓ Ministry of Health (MoH) of the Russian Federation
 - ✓ Organization to which clinical trial applications are submitted
 - ✓ Ensures the quality, safety and efficacy of medicines marketed in Russia
- ✓ Roszdravnadzor:
 - ✓ Control/pharmacovigilance agency
 - ✓ Performs audits on sites and CROs
 - ✓ Receives reports of adverse events and suspected unexpected serious adverse reactions (SUSARs) via the website