



НАДЛЕЖАЩАЯ
ЛАБОРАТОРНАЯ
ПРАКТИКА

GLP in Russia

Marta Bushe
Head of GLP Coordination Center
RusAccreditation



GLP in Russia. History

2012

In 2012, the Government issued an order on the implementation of the OECD GLP principles
Federal Service for Accreditation was appointed as monitoring authority

2013

In April 2013, negotiations were held with the OECD on the format of the GLP system in Russia
Inspectors Trainings

2014

Formation of the regulatory framework
First inspections were carried out



Legislation

Rules of recognition and conformity assessment of the test facilities with good laboratory practice principles,
Approved by Decree of the Russian Government dated December 17, 2013 N 1172.

New version was approved by Decree of the Russian Government dated September 20, 2019 N 1227



Legislation

16 GENERAL
STANDARDS

104 STANDARDS
FOR TEST METHODS

16 general standards on good laboratory practice and 104 standards for test methods were approved, which are translations of the relevant OECD documents from the GLP series and OECD test guidelines



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GLP in Russia

Government policy and regulation



Ministry of Economic Development

Monitoring authority



RusAccreditation

GLP Coordination Centre



National Institute for Accreditation

Receiving authorities



Ministry of Industry and Trade



Ministry of Agriculture



Federal Service for Veterinary and Phytosanitary Surveillance



Ministry of Health



Federal service for surveillance in healthcare



FMBA



Federal Service for Surveillance on Consumer Right Protection and Human Wellbeing



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Inspectors

2 Doctors of science

5 PhD

11 Inspectors participated in the OECD Courses

First list of Russian inspectors was formed in 2013 and consisted of 11 persons.

10 inspectors were trained at the OECD training course in 2013 in Japan, one at the OECD training course in 2015 in India, two at the OECD training course in 2017 in Poland and two at the OECD training course in 2019 in South Africa

Inspectors participated as observers in GLP inspections conducted by foreign monitoring authorities.

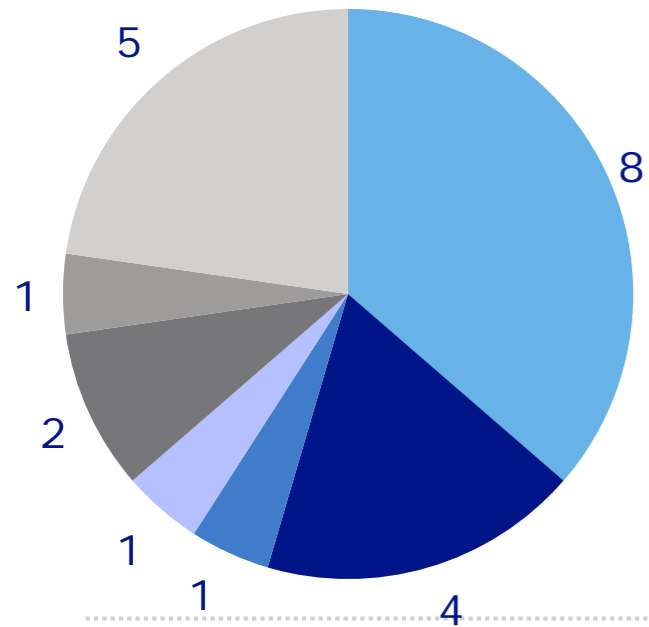


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Test facilities

11 test facilities are included in the national GLP programme

- Medicines for medical use
- Pesticides
- Food additives
- Feed additives
- Cosmetic products
- Medicines for veterinary use
- Industrial chemicals



Cooperation between Russia and the OECD on GLP issues

Representatives of RusAccreditation and the Ministry of Economic Development of Russia annually participate in meetings of the OECD Working Group on Good Laboratory Practice.

The Ministry of Economic Development of Russia jointly with RusAccreditation initiated a project with the OECD "Technical Assistance to Improve the Russian System of Good Laboratory Practice", which aimed to conduct a comprehensive assessment of the Russian GLP system for its compliance with OECD standards.

In July 2019 audit of Russian GLP system was conducted.

Result: **no major, no minor deviations were found**



Thank you
for attention!



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