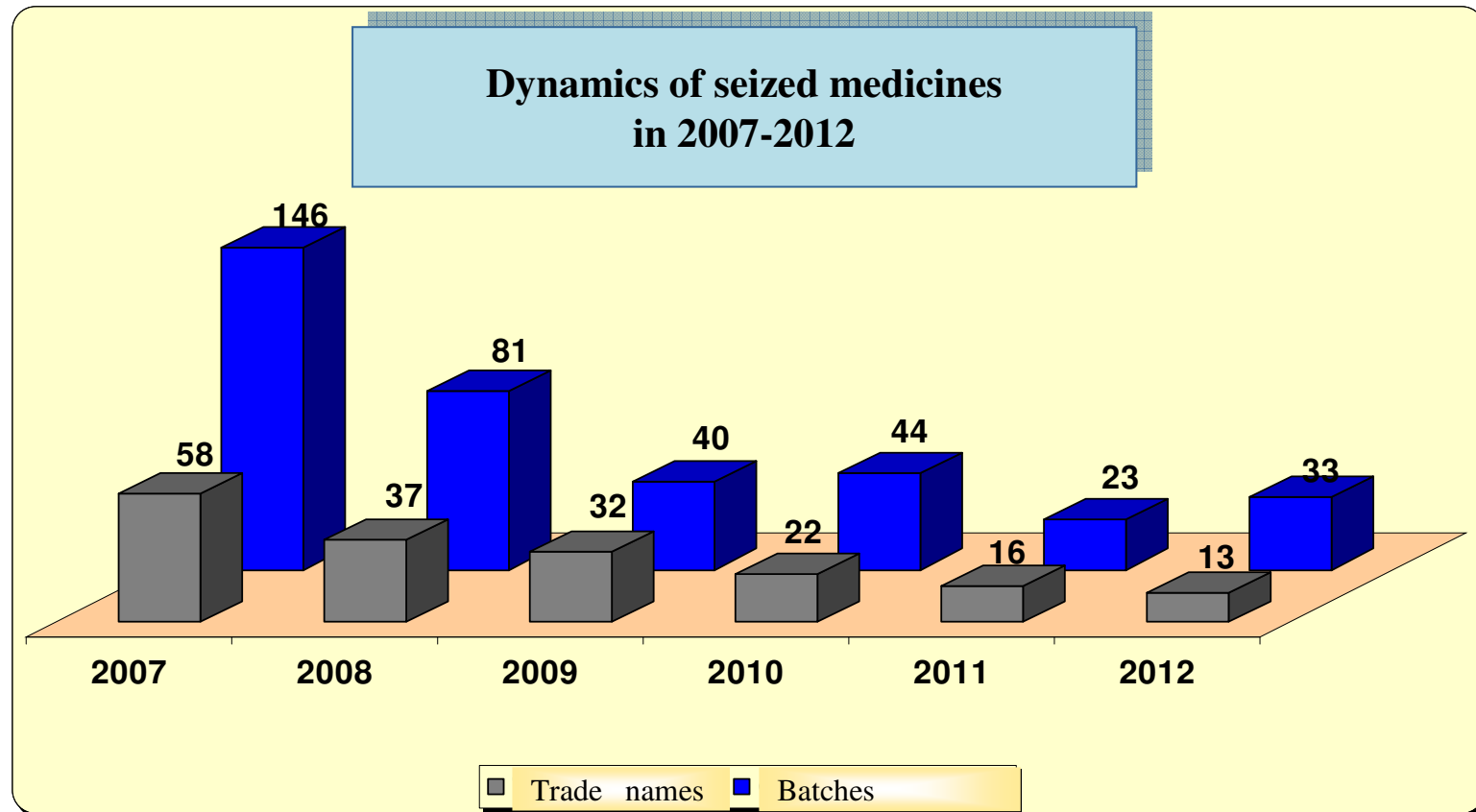


**Federal Service on Surveillance
in Healthcare**



**Counteraction to falsified and
counterfeited medicines circulation
in the Russian Federation.**

The scale of a problem with counterfeit medicines in Russia

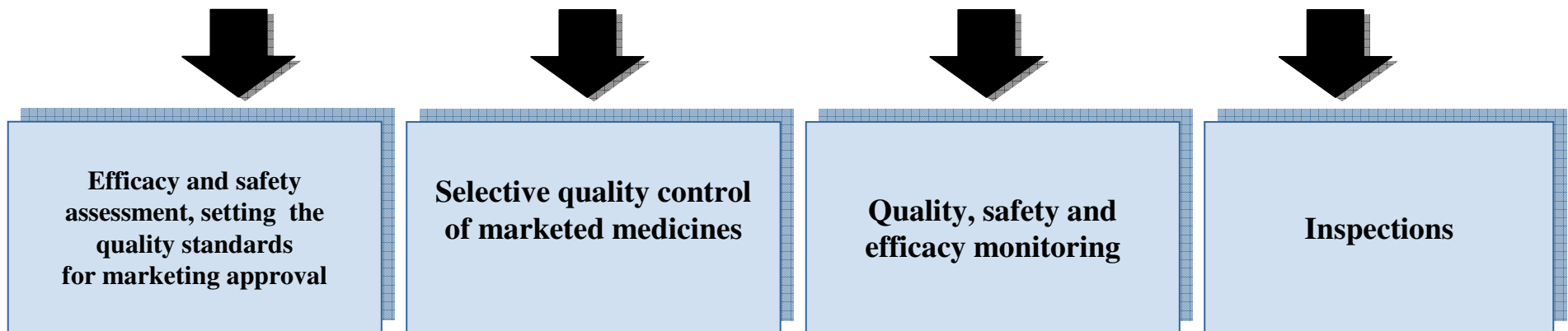


About 1% from circulated on the market is officially detected by Roszdravnadzor as counterfeited, fraudulent and manufactured from counterfeited APIs.

The system of state quality control of medicines



The state system of quality control of medicines



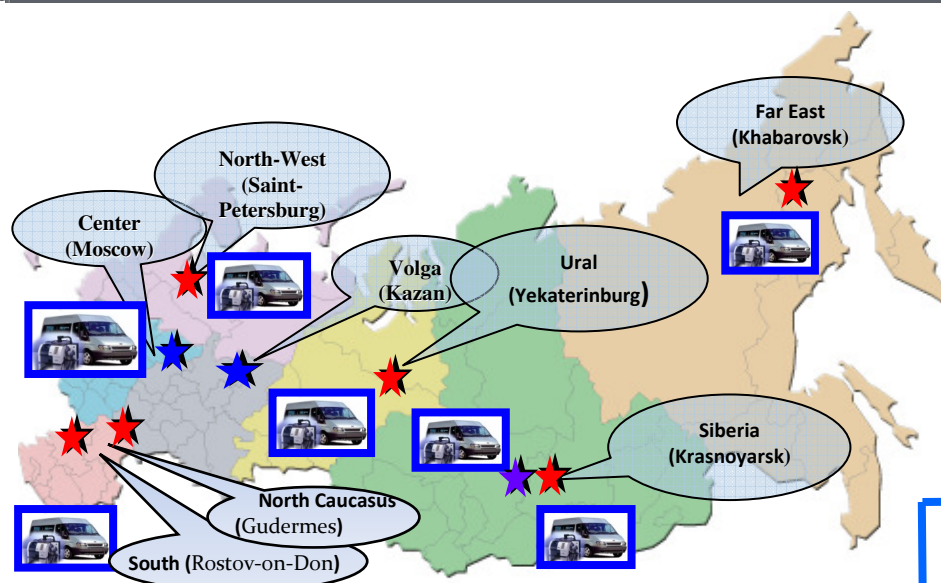
Alongside with Roszdravnadzor, the state control of medicines involves:

- ➔ Regional offices of Roszdravnadzor
- ➔ Quality control laboratories
- ➔ United electronic information resource
- ➔ Quality assurance systems of manufacturers, wholesalers and retailers

Basic elements of the reform of the state quality control of medicines







Mobile express-control laboratories



Since the introduction the **NIR spectroscopy authenticity screening** in 2009 the spectra database has acquired **more than 390** profiles of marketed medicines. The mobile control laboratories are operating in 8 federal districts.

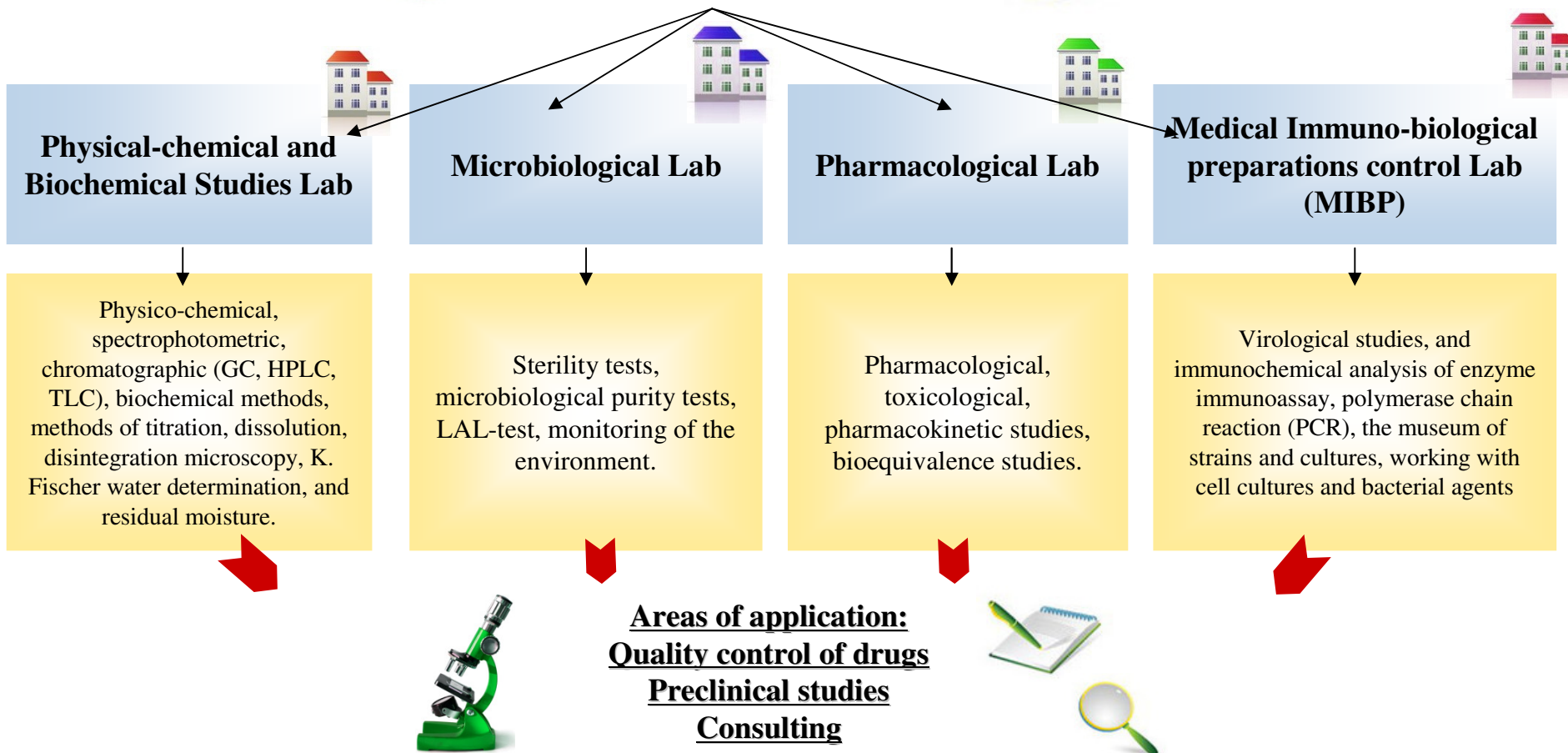
Modern high-tech laboratory complexes began operating in **8 federal districts of the Russian Federation**: Gudermes Rostov-on-Don, Yekaterinburg, Krasnoyarsk, Khabarovsk St. Petersburg. The construction of the laboratory of the Central Federal District is underway in Moscow.



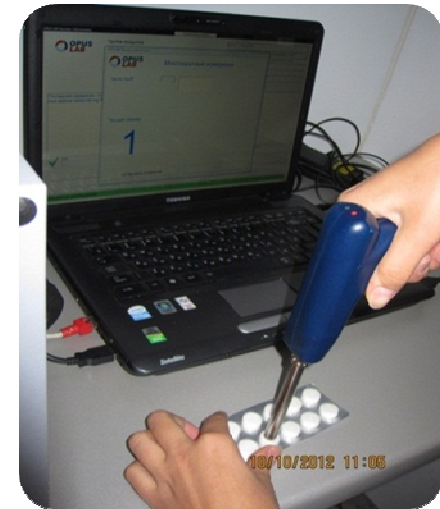
-  Federal laboratory complexes performing quality control of biologicals
-  Inaugurated complexes
-  Federal laboratory complexes with projected facilities for control of biologicals
-  Complexes possessing mobile control laboratories



Medicines Quality Control Laboratory Complex



Mobile Express Laboratories



The pilot project for screening the quality of medicines with the Near Infra Red Spectrometry based on the mobile express laboratories; screening the quality of drugs using non-destructive method. These mobile labs are operating in all Federal Districts of the Russian Federation.

The **NIR spectrometry** for drug identification was introduced in the state system of quality control of medicines in 2009. Since that time, a library of spectra containing **390** medicines was accumulated. The work on the expansion of this library is under way.

Within its competence, Roszdravnadzor maintains inter-agency, institutional and international cooperation.



Law-enforcement agencies

Regular (monthly) information exchange on substandard, falsified and counterfeited medicines with the Ministry of Interior.

Non-governmental institutions

Bilateral cooperation agreements are signed with:

- Association of the Russian Pharmaceutical Manufacturers (**ARPM, APΦΠ**),
- Union of Professional Pharmaceutical Organizations (**UPPO, CΠΦO**),
- Association of International Pharmaceutical Manufacturers (**AIPM**),
- Association of manufacturers of Pharmaceutical products and medical devices (**AΦΠ**).

International cooperation

- ❖ The international cooperation provides Roszdravnadzor with valuable data on quality of medicines contributing to efficient struggle against counterfeit and low-quality products.
- ❖ Roszdravnadzor signed bilateral memoranda and maintains effective cooperation with the drug regulators from China, European states, USA, Ukraine and others.
- ❖ Roszdravnadzor was involved into elaboration of **CoE's Medicrime convention**. Russia signed the Convention on the day of its opening for signature (October, 28th, 2011).

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Thank you for your attention!