MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

GMP VIII ALL-RUSSIA GMP CONFERENCE

50 years GXP SID& GP

Typical deficiencies founded during inspections

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Yekaterinburg city
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Структура фармацевтического инспектората Республики Казахстан

Committee for medical and pharmaceutical control of the Ministry of Health of the Republic of Kazakhstan

- Department of Pharmaceutical Inspectorate and Integration of the Committee
- Territorial branches of the Committees

15 GMP inspectors

Inspections of sites located on the territory of the Republic of Kazakhstan

Republican State Enterprise on the right of economic management "National Center for Expertise of Medicines and Medical Devices" of the CMPC MoH RK

- Subdivision of Pharmaceutical Inspectorate of the Department of Inspections

10 GMP inspectors

Inspections of sites located outside the territory of the Republic of Kazakhstan

Regulatory acts regulating pharmaceutical inspections

- The Decision of the Council of the Eurasian Economic Commission № 83 dated November 3, 2016 “On Approval of the Rules for Conducting Pharmaceutical inspections”
- The Decision of the Council of the Eurasian Economic Commission № 127 dated August 19, 2022 "On Amendments to the Rules of Pharmaceutical Inspections”
- The Order of the Minister of Health of the Republic of Kazakhstan № KR DSM-9 dated January 27, 2021 "On approval of the rules for conducting pharmaceutical inspections on appropriate pharmaceutical practices”
- Inspections are carried out on the basis of the application of the subject of inspection or by the decision of the authorized body

НАЦИОНАЛЬНЫЙ ЦЕНТР ЭКСПЕРТИЗЫ ЛЕКАРСТВЕННЫХ СРЕДСТВ И МЕДИЦИНСКИХ ИЗДЕЛИЙ

Pharmaceutical inspections for compliance with the requirements of GMP of the EAEU for 2021-2023

Inspections were carried out in 2021-2023

69

(including local manufacturers-12)

59 (including local manufacturers-11) issued EAEU certificates

2 refused to issue

1 report is being formed (for 2023)

Number of applications received

104

(for 2021-2023)

34 Planned (for the 4th quarter of 2023 - 23, for 2024 - 14)

5 Postponed applications

11 Withdrawal of the application

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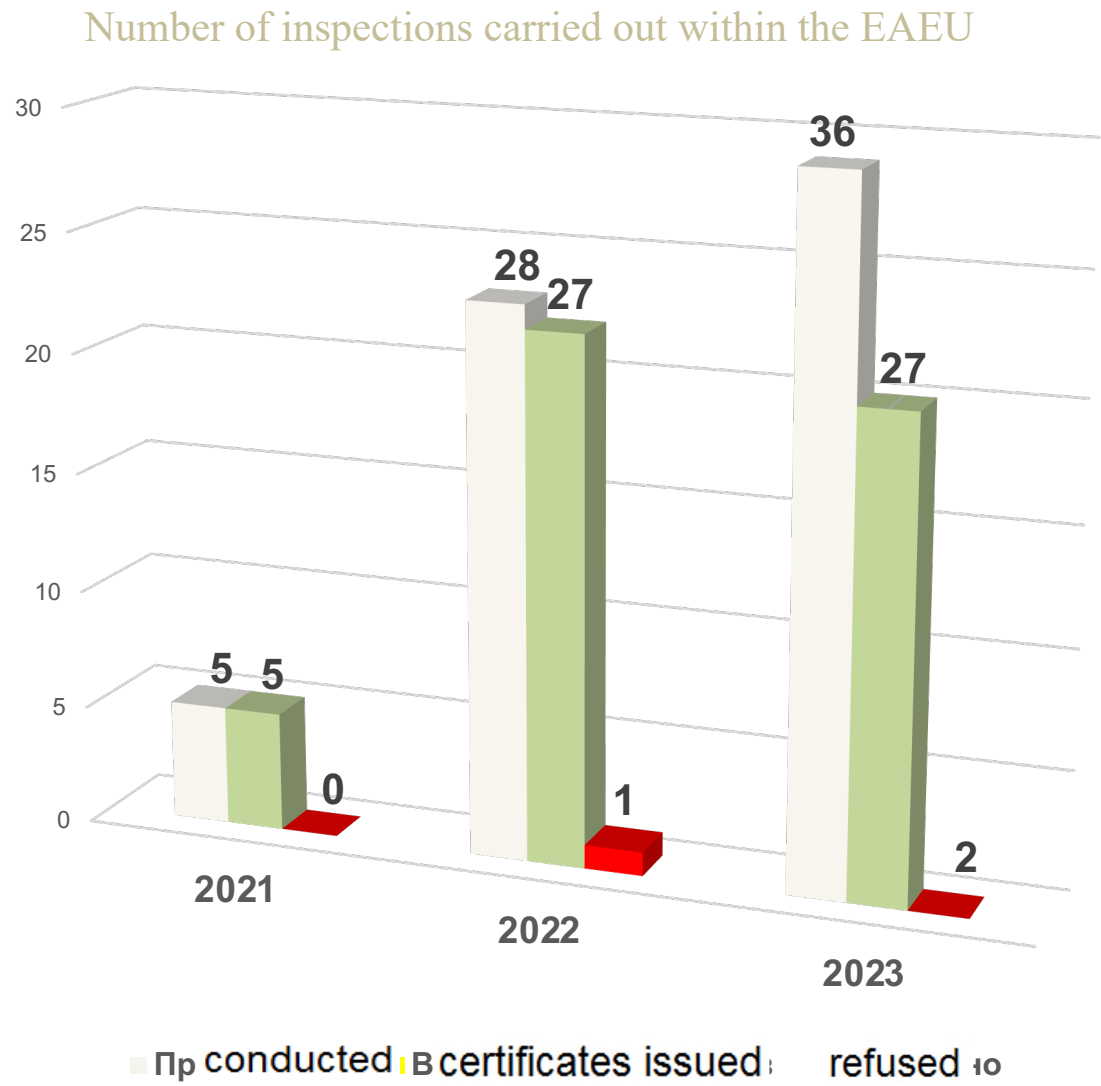

The most frequent critical and significant deficiencies founded during the inspection

1. the production of the medicinal product does not correspond to the registration dossier
2. lack of validation and qualification of premises, systems, equipment, lack of records on the qualification of clean rooms, critical equipment, water treatment systems, compressed air preparation systems
3. not ensuring the appropriate condition and the required level of cleanliness in clean rooms
4. lack of confirmation (validation) of time intervals between the end of one technological process before another
5. failure to ensure orderly storage of various categories of materials and products and failure to comply with proper storage conditions for incoming raw materials and materials

Tasks

1. Cooperation with international organizations and regulators
2. Preparation of an application to PICs (Pharmaceutical Inspection Cooperation Scheme)
3. Achieving the 3rd level of maturity of WHO Benchmarking
4. Continuous professional development and training of pharmaceutical inspectors

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