
State Institute
of Drugs
and Good Practices
MINPROMTORG
RUSSIA

Russian Pharmaceutical Inspectorate Structure

Ministry of Industry and Trade of the Russian Federation

Issuing the Manufacturer's Certificates of Conformity with the requirements of the EAEU Good Manufacturing Practice Rules

Department of Pharmaceutical and Medical Industry Development

Licensing of drug products manufacture in the Russian Federation.

FSI «State Institute of Drugs and Good Practices» (FSI «SID & GP»)

Inspection of subjects of medicines circulation in accordance with the Order No. 90 dated January 20, 2021, of the Ministry of Industry and Trade of Russian Federation.

Since 2015, FSI «SID & GP», as a subordinate institution of the Ministry of Industry and Trade of the Russian Federation, has been authorized to conduct inspections of pharmaceutical manufacturers' sites for compliance with the requirements of the Good Manufacturing Practice Rules.

Regulatory documents of Eurasian Economic Union

Treaty on the Eurasian Economic Union of 29 May 2014 (revised on 1 October 2019)

Agreement on Common Principles and Rules for the Circulation of Medicines within the Eurasian Economic Union, of 23 November 2014

Decision No. 83, of the Council of the Eurasian Economic Commission, of 3 November 3 2016, On approval of the Rules for conducting pharmaceutical inspections;

Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 No. 77 harmonized with the European GMP-Rules (Eudralex The Rules Governing Medicinal Products in the European Union)

Decision No. 93 of the Council of the Eurasian Economic Commission, of 3 November 2016, On the recognition of the results of inspection of drug production

Risk assessment and Express assessment of the complexity of the inspection

List of medicines declared for inspection (A)

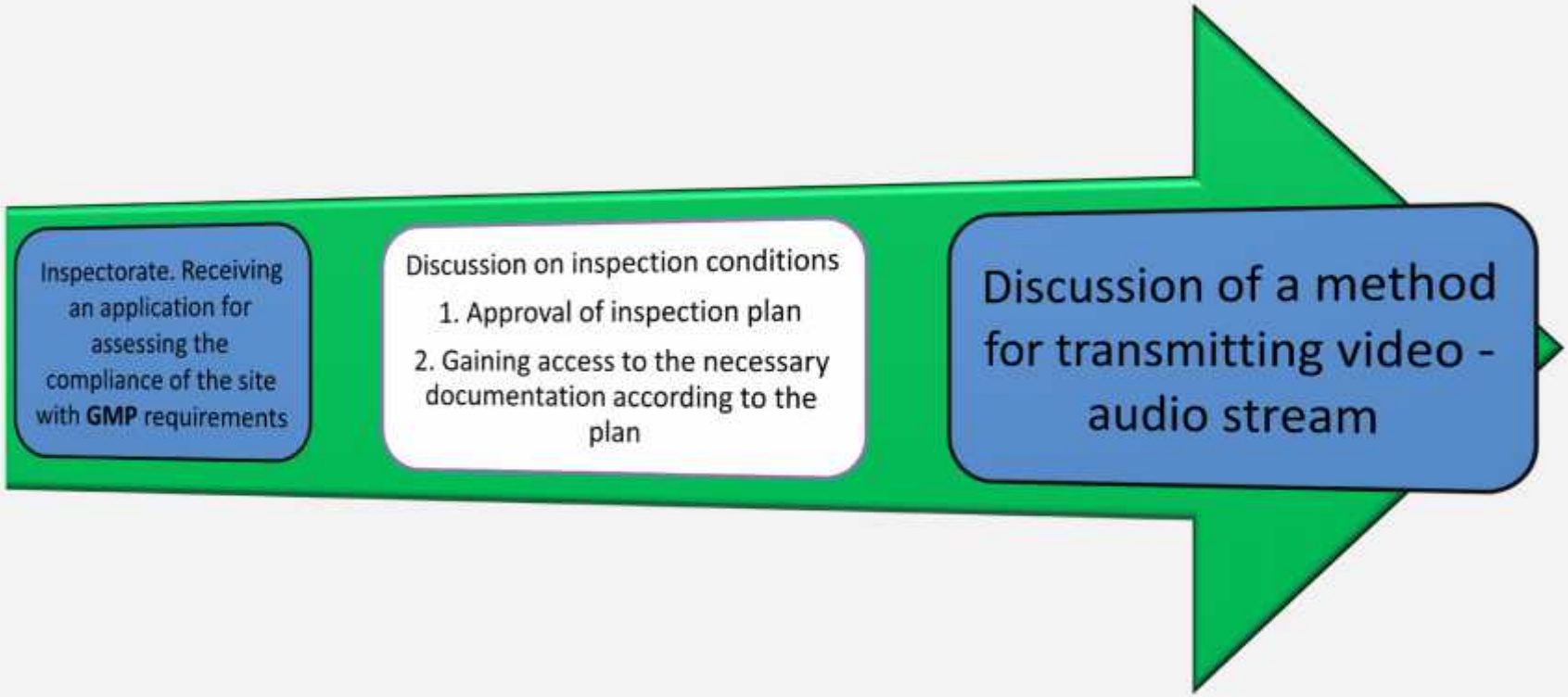
- 6. Sterile drugs: biotechnological products, vaccines, human plasma/blood products, radiopharmaceuticals, advanced therapy medicinal products ASEPTIC PROCESS
- 5. Sterile drugs: FINISHING STERILIZATION
- 4. Non-sterile drugs
- 3. Primary packaging
- 2. Secondary packaging
- 1. Releasing quality control (CoC)

Type of inspection (B)

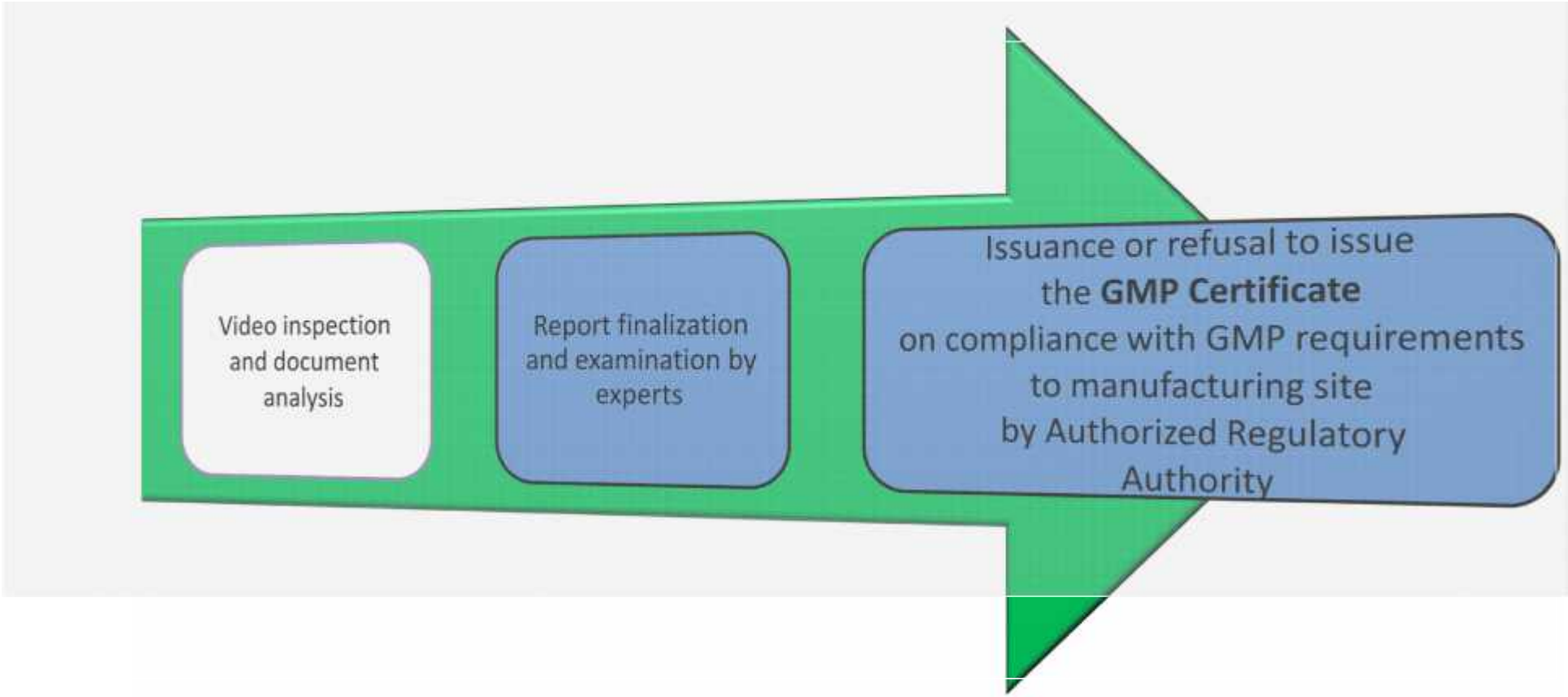
- 5. Re-inspection after refusal
- 4. New list of medicines after refusal
- 3. Re-inspection with a new list of medicines
- 2. GMP confirmation (the site already has a GMP certificate)
- 1. Adding/changing the site address

A×B= risk level and need for on site inspection

Remote inspection



Remote inspection



Thanks for your attention.

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For consultations on inspection of foreign drug manufacturers, please call us at:
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Work schedule: Mon-Fri from 9.00 to 18.00