

**THE XXIIIth CONFERENCE  
«STATE REGULATION IN THE SPHERE OF MEDICINE  
AND MEDICAL DEVICES CIRCULATION»  
«PharmMedCirculation 2021»**

# PROGRAM

**10–11**  
June  
**2021**  
Moscow  
online live

**CDMO** ФАРММЕДОБРАЩЕНИЕ  
**2021**

# SHORT PROGRAM

## Schedule of events June 10

---

### Hall 1

---

**09.30–13.00** Plenary session

**14.00–18.15** Session — *Improving the system of state quality control of medicines*

---

### Hall 2

---

**14.00–16.00** Session — *Registration of medical devices within the EAEU. Prospects of development and current challenges*

**16.15–18.15** Round table — *Features of circulation of medical devices*

---

---

## Schedule of events June 11

---

### Hall 1

---

**09.00–13.15** **Session** — *Lessons from the pandemic in medicine provision. Vaccination experience*

---

**14.15–17.00** **Session** — *Healthcare digitalization in Russian Federation. System for monitoring the movement of medicines*

---

### Hall 2

---

**09.00–11.00** **Session** — *Development of the pharmacy and wholesale organizations in modern conditions taking into account the development of control and supervisory activities*

---

**11.15–13.15** **Session** — *Organization and procurement of medicines: prospects of work and development in modern conditions*

---

**14.15–16.00** **Session** — *Development of legal regulation of the circulation of medical devices: step forward*

---

**16.15–18.15** **Session** — *State control over the circulation of medical devices on the territory of the Russian Federation*

---

# CONFERENCE PROGRAM

## June 10

**June 10**  
**09.30–13.00**  
**Hall 1**

**Plenary session**  
With simultaneous  
translation

**Murashko M.A.** — Minister of Health of the Russian Federation

**Samoylova A.V.** — Head of the Federal Service for Surveillance in Healthcare

**Nazarenko V.V.** — member of the Board (Minister) for technical regulation of the Eurasian economic Commission

**Osmakov V.S.** — the First Deputy Minister of industry and trade of the Russian Federation

**Petina I.A.** — member of the Federation Council Committee on social policy of the Federal Assembly of the Russian Federation

**Petrov A.P.** — member of the State Duma Committee on Health Protection of the Federal Assembly of the Russian Federation

**Vdovin A.V.** — Director of the Department of state policy in the field of licensing, control and supervisory activities, accreditation and self-regulation of the Ministry of Economic Development of the Russian Federation

**Vujnović M.** — the representative of the World Health Organization in Russia

**Keitel S.** — Director of the European Directorate for quality of medicines and health of the Council of Europe (EDQM)

**Piervincenzi R.** — Director of the United States Pharmacopoeia Convention (USP)

### Improving the system of state quality control of medicines

*Moderators:* **Parkhomenko D.V.** — Deputy Head of Roszdravnadzor, **Trapkova A.A.** — Deputy of the General Director of the FGBU “NTSESMP” of the Ministry of Health of Russia

- Results of the state quality control of medicines in the new conditions of release into civil circulation (**Kudryavtseva E.M.** — Head of the Department of state quality control of medical products of Roszdravnadzor)
- Trend analysis of quality of immunobiological medicines in the consolidated protocols of the manufacturers (**Movsesyants A.A.** — Head of testing center of the MIBP of the FGBU “NTSESMP” of the Ministry of Health of Russia, **Yakunin D.Yu.** — Head of center of expertise and development of methods of quality control of immunobiological products of the FGBU “MTSEUAOSMP” of Roszdravnadzor)
- The EEC approaches to regulating the circulation of medicines (**Rozhdestvensky D.A.** — Head of the Department for coordination of work in the field of circulation of medicines and medical devices of the Department of technical regulation and accreditation of the Eurasian economic Commission)
- The EAEU Pharmacopoeia requirements (**Tulegenova A.U.** — Chairman of the Pharmacopoeia Committee of the Eurasian Economic Union, Head of the Center for Improvement of the GF RK and the Pharmacopoeia of the EAEU RGP on PHV “National Center for Expertise of Medicines and Medical Devices” of the Ministry of Health of the Republic of Kazakhstan)
- European approaches to the regulation of nitrosamine impurities in medicines (**Wierer M.** — Head of the Medicines Division, Department of Biological Standardization, OMCL Network and Healthcare, EDQM)
- USP approach to the regulation of nitrosamine impurities in medicines (**Gump E.** — USP vice-president)
- Features of the application of mass spectrometry methods for the analysis of impurities in medicinal products (**Koshkin S.A.** — Head of the Center for Mass Spectrometric Analysis of the Yaroslavl branch of the FGBU “MTSEUAOSMP” of Roszdravnadzor)

June 10  
14.00–18.15  
Hall 1

**Session**  
With simultaneous  
translation

# CONFERENCE PROGRAM

June 10  
14.00–16.00  
Hall 2

## Session

### Registration of medical devices within the EAEU. Prospects of development and current challenges

*Moderators:* **Astapenko E.M.** — Director of the Department of medicine provision and regulation of medical devices of the Ministry of Health, **Pavlyukov D.Yu.** — Deputy Head of Roszdravnadzor, **Yakutova M.A.** — Head of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor, **Sukhanova M.M.** — Deputy Head of the Department for Organization of State Control and Registration of Medical Devices of Roszdravnadzor, **Ivanov I.V.** — General Director of the FGBU “National institute of quality” of Roszdravnadzor

- Review of legal regulation in the sphere of medical devices circulation within the Eurasian economic Union (**Shchekin D.A.** — Deputy Head of the Division of coordination of work in the field of circulation of medicines and medical devices of the Department for technical regulation and accreditation of the Eurasian economic Commission)
- The registration procedure of medical devices in the Eurasian Economic Union (**Esbolatova D.E.** — specialist of the 1st category of the scientific educational Center of the Republican State Enterprise on the Right of Economic Management “National Center for Medicine and Medical Devices Expertise” of the Committee for quality control and safety of goods and services of the Ministry of Health of the Republic of Kazakhstan)
- Typical mistakes in preparing a set of documents for registration of medical devices (**Pika T.O.** — the Department for Organization of State Control and Registration of Medical Devices of Roszdravnadzor)
- Inspection of production of medical devices (**Akhtyamov E.I.** — Deputy Head of the Department of licensing and control of compliance with mandatory requirements of Roszdravnadzor)
- Clinical trials of medical devices in the EAEU: problems and solutions (**Parakhina S.B.** — Head of the Registration and Certification Department (Russia and the CIS) of “RP Canon Medical Systems LLC”)
- Answers to the questions

## Features of circulation of medical devices

**Moderators:** **Astapenko E.M.** — Director of the Department of medicine provision and regulation of medical devices of the Ministry of Health, **Pavlyukov D.Yu.** — Deputy Head of Roszdravnadzor, **Yakutova M.A.** — Head of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor, **Sukhanova M.M.** — Deputy Head of the Department for Organization of State Control and Registration of Medical Devices of Roszdravnadzor, **Ivanov I.V.** — General Director of the FGBU “National institute of quality” of Roszdravnadzor

- Peculiarities of registration of medical devices during the pandemic (**Vorobyeva E.A.** — the Head of the Division of registration of medical devices of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor)
- Legal regulation of software as medical device. Development prospects (**Pika T.O.** — the Department for Organization of State Control and Registration of Medical Devices of Roszdravnadzor)
- Import of medical devices. Practical aspects. Features of import of medical devices in accordance with the decree of the Government of the Russian Federation of 03.04.2020 No. 430 (**Kuznetsova T.D.** — Department of monitoring of medical devices and maintaining registers of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor)
- Answers to the questions

June 10  
16.15–18.15  
Hall 2

Round table

## June 11

**June 11**  
**09.00–13.15**  
**Hall 1**

**Session**  
With simultaneous  
translation

### **Lessons from the pandemic in medicine provision. Vaccination experience**

- Moderators:** **Kosenko V.V.** — Acting Director General of the FGBU “NTSESMP” of the Ministry of Health of Russia, **Cooke E.** — Director of the European Medicine Agency — EMA
- Accelerated introduction of medical products to the market (**Romanov F.A.** — Director of the Department of state regulation of the circulation of medicines of the Ministry of Health of the Russian Federation)
  - Overview of the regulatory measures taken in Europe to combat coronavirus infection (**Cooke E.** — Director of the European Medicine Agency — EMA)
  - Pharmaceutical inspections experience during the pandemic (**Shestakov V.N.** — Director of the FBU “GILS and NP” of the Ministry of Industry and Trade of Russian Federation)
  - Issues of control of clinical trials of medicines in the pandemic conditions (**Murzich T.V.** — the Deputy Head of the Division of clinical trials control of the Department of organization of state quality control of medical products of Roszdravnadzor)
  - Organization of medicines safety monitoring during the COVID-19 pandemic (**Gorelov K.V.** — Deputy Head of the Department — Head of the pharmacovigilance division of the Department of state quality control of medical products of Roszdravnadzor)
  - Good regulatory practices and good reliance practices of WHO (**Azatyanyan S.** — Team Lead Regulatory Convergence and Networks [RCN], Regulation and Safety [REG], Regulation and Prequalification [RPQ], World Health Organization)

## Development of the pharmacy and wholesale organizations in modern conditions taking into account the development of control and supervisory activities

*Moderators:* **Krupnova I.V.** — Head of the Department of licensing and control of compliance of Roszdravnadzor, **Semecheva S.V.** — Deputy Director of the Department of medicine provision and regulation of the circulation of medical devices of the Ministry of Health of Russia

- Public and professional audit-independent assessment of compliance with mandatory requirements (**Litvinova M.V.** — Executive Director of “Soyuz-Pharma”)
- Online sale of medicines, experience and prospects (**Semecheva S.V.** — Deputy Director of the Department of medicine provision and regulation of the circulation of medical devices of the Ministry of Health of Russia)
- Development of pharmacy organizations in modern conditions (**Nevolina E.V.** — Executive Director of the noncommercial partnership “Pharmaceutical Chamber”)
- Validation and mapping as an element of the quality management system (**Astafyev S.V.** — expert on cold chain validation at Valli Technology)
- Responsible person, his powers, rights and responsibilities in selling high — quality and effective medicines (**Starostina I.S.** — Head of the Department of licensing and monitoring compliance with mandatory requirements of Roszdravnadzor)
- Modern realities in the activities of pharmacy organizations (**Ignatieva N.V.** — Executive Director of the Russian Association of pharmacy networks)
- Perspectives of development of online sales (**Bykov A.V.** — Director of the Department of healthcare economics of JC “R-Pharm”)

June 11  
09.00–11.00  
Hall 2

Session

June 11  
11.15–13.15  
Hall 2

## Session

### Organization and procurement of medicines: prospects of work and development in modern conditions

*Moderator: Astapenko E.M.* — Director of the Department of Medicine Provision and Regulation of Medical Devices of the Ministry of Health of Russia

- Modern issues of medicine provision (*Astapenko E.M.* — Director of the Department of Medicine Provision and Regulation of Medical Devices of the Ministry of Health of Russia)
- Organization and procurement of medicines: prospects for the work and development of the Federal center for planning and medicine provision of citizens (*Maksimkina E.A.* — Director of the Federal State Institution “Federal Center for planning and organization of medicine provision for citizens” of the Ministry of Health of the Russian Federation)
- New approaches to the pricing and to the medicine procurement: advantages and realization possibilities in the Russian Federation (*Musina N.Z.* — Head of the Department of development and communications of the Federal State Budgetary Institution “Center for expertise and quality control of medical care” of the Ministry of Health of the Russian Federation)
- Prospects for the transition to the system of medicine reimbursement in the Russian Federation (*Fedyayev D.V.* — Head of the Department of Methodology of Healthcare Informatization of the Federal State Budgetary Institution “Center for expertise and quality control of medical care” of the Ministry of Health of the Russian Federation)
- Long-term contracts: prospects and limitations (*Bykov A.V.* — Director of the Department of healthcare economics of JC “R-Pharm”)
- Preparation of an application for a medicine for the treatment of SMA: what clinical and economic factors to consider (*Kulikov A.Yu.* — Professor of the Department of Organization of Medicine Supply and Pharmacoeconomics of the Sechenov University) — with the support of the company “Johnson & Johnson”

**Healthcare digitalization in Russian Federation. System for monitoring the movement of medicines**

*Moderators:* **Pugachev P.S.** — Deputy Minister of Health of the Russian Federation, **Kudryavtseva E.M.** — Head of the Department of Organization of State Quality Control of Medical Products of Roszdravnadzor, **Pospelov K.G.** — Deputy Head of the Administration Department of Roszdravnadzor

- Presentation (**Merkulova E.E.** — Deputy Director of the Department of Digital Development and Information Technologies of the Ministry of Health of the Russian Federation)
- Digital transformation of regulatory processes of medicine circulation. International trends and experience of the EAEU. Industry View (**Popova E.Y.** — Senior Director for Regulatory Affairs and Health Policy of AIPM)
- Development of systems for monitoring the movement of medical products in the Russian Federation (**Tukhvatullin O.V.** — Deputy Director of the Department of digital labeling of goods and legalization of product circulation of the Ministry of Industry and Trade of the Russian Federation)
- Functioning of the system for monitoring the movement of medicines for medical use. Questions, problems, solutions (**Zhavoronkov E.** — Head of the product group “Pharma” of the Center for the Development of Perspective Technologies)
- Experience of the Territorial bodies of Roszdravnadzor in working with the MDLP system (**Zamiralova T.B.** — Head of the Territorial Body of Roszdravnadzor in the Yaroslavl region, **Chebotareva N.I.** — Head of the Control Department in the field of medicine circulation of the Territorial body of Roszdravnadzor in Moscow and the Moscow region)
- View of a distributor of medicines (**Galyamova V.V.** — Executive Director of JSC NPK “Katren”)
- View of a healthcare organization (**Borshchevskaya N.A.** — Head of information technology Department of GBUZ “GKB named after M.P. Konchalovsky DZM”)
- The issue of labeling of medicines in the domestic pharmaceutical companies, the experience of a Biochemist (**Zemskov D.** — Executive Director of JSC “Biochemist” (GK “Promomed”))

**June 11**  
**14.15–17.00**  
**Hall 1**

**Session**

# CONFERENCE PROGRAM

June 11  
14.15–16.00  
Hall 2

## Session

### Development of legal regulation of the circulation of medical devices: step forward

*Moderators:* **Astapenko E.M.** — Director of the Department of medicine provision and regulation of medical devices of the Ministry of Health of Russia, **Pavlyukov D.Yu.** — Deputy Head of Roszdravnadzor, **Binko K.A.** — Deputy Director of the Department of Medicine Provision and Regulation of Medical Devices of the Ministry of Health of Russia

- Novelties of legislation in the field of regulation of the circulation of medical devices (**Binko K.A.** — Deputy Director of the Department of Medicine Provision and Regulation of Medical Devices of the Ministry of Health of Russia)
- Application of the catalog of goods, works and services in the procurement of medical devices (**Sapunova A.V.** — Deputy Head of the Department of Nomenclature classification, expertise and inspection of the production of medical devices of the Federal State Budgetary Institution “National Institute of Quality” of Roszdravnadzor)
- National project “Healthcare”: procurement of medical devices (**Plutnitskiy A.N.** — Director of the Department of Project Activities of the Ministry of Health of the Russian Federation)
- Single market of circulation of medical devices of the EAEU: regulation 2022-2026 (**Lobastova E.S.** — Deputy Head of the Department of regulation of circulation of medical devices of the Department of medicine supply and regulation of circulation of medical devices of the Ministry of Health of the Russian Federation)

## State control over the circulation of medical devices on the territory of the Russian Federation

**Moderators:** *Pavlyukov D.Yu.* — Deputy Head of Roszdravnadzor, *Yakutova M.A.* — Head of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor, *Migeeva M.A.* — Deputy Head of the Department for organization of state control and registration of medical devices of Roszdravnadzor

- Changes in legislation for the state control over the circulation of medical devices in the near future (*Kudjaev V.N.* — Head of the Division of organization of state control of the circulation of medical devices of the Department for organization of state control and registration of medical devices of Roszdravnadzor)
- Typical nonconformities detected during tests and studies during the state control over the circulation of medical devices (*Rybalov A.A.* — Acting Head of the Testing center of the Federal State Budgetary Institution “VNIIMT” of Roszdravnadzor)
- Novelties of licensing in maintenance of medical devices (*Akhtyamov E.I.* — Deputy Head of the Department of licensing and control of compliance with mandatory requirements of Roszdravnadzor)
- Changes in the legal regulation of monitoring the safety of medical devices (*Ivanova T.V.* — Head of the Department of monitoring of medical devices of the Federal State Budgetary Institution “VNIIMT” of Roszdravnadzor)

June 11  
16.15–18.15  
Hall 2

Session

Please note that the conference organizing Committee reserves the right to make changes to the program and the list of speakers