THE XXIIth CONFERENCE «STATE REGULATION IN THE SPHERE OF MEDICINE AND MEDICAL DEVICES CIRCULATION» «PharmMedCirculation 2020»

October 29-30 2020, Moscow, online live

October 28

Competition
Safety of medical devices – for the welfare of people

CONFERENCE PROGRAM

October 29

9.30-12.30
Plenary session
With simultaneous translation

M. A.Murashko – Minister of Health of the Russian Federation
I. Yu. Svyatenko– Chairman of the Federation Council Committee on social policy of the Federal Assembly of the Russian Federation
A. P. Petrov– member of the State Duma Committee on health protection of the Federal Assembly of the Russian Federation
S. A. Tsyb – First Deputy Minister of industry and trade of the Russian Federation
V. V. Nazarenko – member of the Board (Minister) for technical regulation of the Eurasian economic Commission
M. Vujnović – the representative of the World Health Organization in Russia
S. Keitel – Director of the European Directorate for quality of medicines and health of the Council of Europe (EDQM)
G.Rasi – Director of the European Medicines Agency (EMA)
R. Piervincenzi – Director of the United States Pharmacopoeia Convention (USP)
A.V. Samoilova – Head of the Federal Service for Surveillance in Healthcare

Summing up the results of the competition "Safety of medical devices - for the welfare of people»

Hall 2
13.30-15.30
Session
Issues of registration of medical devices within the EAEU. Basic errors in the preparation of documents
Moderators: **Astapenko E.M.** – 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 framework of the Eurasian economic Union (**Dzhusupova D. D.** - Deputy Director Of the Department for technical regulation and accreditation of the Eurasian economic Commission)
- The registration procedure of medical devices in the Eurasian economic Union (**Abdymanova B. J.** – Acting Director of territorial branch in Almaty of the Republican State Enterprise on the Right of Economic Management "National Center for Medicine, Medical Devices Equipment Expertise" of the Committee for quality control and safety of goods and services of the Ministry of Health of the Republic of Kazakhstan)
- Main mistakes in preparing a set of documents for registration of medical devices (**Pika T.O.** – leading consultant of the Department of registration of medical devices of the Division 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)

Hall 3
13.30-15.30
Session
Development of the pharmaceutical industry pharmacy and wholesale organizations in modern conditions taking into account the development of control and supervisory activities

Moderator: **Krupnova I.V.** - Head of the Division of Licensing and Control of Compliance of Roszdravnadzor

- Current trends in the development of control and supervisory activities. New forms of control (**Krupnova I.V.** - Head of the Division of Licensing and Control of Compliance of Roszdravnadzor)
- New legislation regulating the activities of medical organizations, distributors and pharmacies in the circulation of medicines, including narcotic drugs and psychotropic substances (**Panova O.S**. - Head of the Department of Legal Regulation of Pharmaceutical Activities, Circulation of Narcotic and Psychotropic Substances of the Ministry of Health of Russia
- Current trends in the development of the pharmacy industry. Work of pharmacies in 2020 (**Ignatieva N.V.** - Executive Director of the Russian Association of Pharmacy Chains)
- Results and ways of development of control and supervisory activities in the field of medicine regulation. First results of the use of labeling in the control activities of the territorial body (**Chebotareva N. I.** – Head of the Department of control in the sphere of circulation of medicines of the territorial body of Roszdravnadzor in Moscow and Moscow region)
- "Cold chain": how to maintain the quality of medicines and vaccines at all stages (**Efimov D. V.** – General Director of Immunotechnologies LLC)

Hall 1
14.00-18.00
Session
Implementation of a system for monitoring the movement of medicines for medical use
With simultaneous translation

Модераторы: **Kosenko V.V.** – Deputy Head of Roszdravnadzor, **Kholkin S. I.** – Head of the pharmaceutical direction of LLC "Operator-CRPT»

- Regulatory and legal regulation of medicines labeling during the transition period (**Kosenko V. V.** – Deputy Head of Roszdravnadzor)
- The first results of the introduction of the system for labeling medicines by means of identification (**Kudryavtseva E. M.** – Deputy Head Of the Department of state quality control of medical products of Roszdravnadzor)
- Functioning of the system for monitoring the movement of medicines for medical use. Questions, problems, solutions (K**holkin S. I.** – Head of the pharmaceutical direction of LLC "Operator-CRPT»)
- View of a domestic manufacturer of medicines (**Shorikov R. V.** – Deputy Director for supply chain management for the EAEU countries of Servier LLC)
- View of a foreign manufacturer of medicines (representative of JSC Gideon Richter)
- Labeling of medicines in a customs warehouse. Implementation experience (**Kurasheva S. V.** – adviser to the President of the group of companies "Santens Service" on operations development)
- View of the distributor of medicines (representative of CJS CV PROTEK)
- View of a pharmacy chain or Association (representative of RIGLA LLC)
- View of the medical organization (**D. N. Nikitenko** – first Deputy General Director of the Pirogov University of the Ministry of health of the Russian Federation)
- Labeling and monitoring the movement of medicines: the need to optimize processes (**Bykov A.V**. – Director of Health Economics of R-Pharm JSC)

Hall 2
15.45-17.45
Round table
Features of circulation of medical devices

Moderators: **Astapenko E.M.** – Head of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor, **Akhtyamov E. I.** – Deputy Head of the Department of licensing and control of compliance with mandatory requirements of Roszdravnadzor, **Ivanov I.V.** - General Director of the FGBU “National institute of quality” of Roszdravnadzor

- Novelties of production and maintenance of medical devices from 2021 (**Akhtyamov E. I.** – Deputy Head of the Department of licensing and control of compliance with mandatory requirements of Roszdravnadzor)
- Ways of development in the field of regulatory regulation of software as a medical device (**Astapenko E.M.** – Head of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor)
- The import of medical devices: a new model of state service (**Anokhina E. V.** – Deputy Head of monitoring medical devices and keeping registers of the Department of organization of state control and registration of medical devices of Roszdravnadzor)
- The implementation of the catalogue of medical devices in state procurement (**Kazmin I.A.** - Deputy Director General of the FGBU “National Institute of Quality” of Roszdravnadzor)

Hall 3
15.45-17.45
Session
Quality management system in pharmaceutical activity. Problems and reality
Moderators: **Parkhomenko D.V.** - Deputy Head 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, **Krupnova I.V.** - Head of the Department of Licensing and Control of Compliance of Roszdravnadzor

- 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)
- Manufacturing in a pharmacy organization in modern conditions, ways of development (**Nevolina E. V.** – Executive Director of the Union "National Pharmaceutical Chamber")
- The role of a pharmaceutical specialist in the work of a pharmacy organization (**Ignatieva N. V.** – Executive Director of the Russian Association of pharmacy chains)
- Legalisation of distant selling of medicinal products. First results, problems and ways of development (**Krupnova I.V.** - Head of the Department of Licensing and Control of Compliance of Roszdravnadzor)

October 30

Hall 1
09.15-11.15
Closed session
Regulators of medical devices: exchange of experience. Problems of circulation of medical devices for in vitro diagnostics in conditions of coronavirus infection
With simultaneous translation

Moderators: **Astapenko E.M.** – Head of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor, **Burykina T. Y. –** the expert of Department of examination of quality, efficacy and safety of medical devices of the FGBU "National institute of quality" of Roszdravnadzor

- Circulation of medical devices for in vitro diagnostics of Covid-19 in a pandemic. Experience of countries and regions:
  - **Momynaliev K. T.** – expert of the Department of nomenclature classification, examination and inspection of production of medical devices of the FGBU "National Institute of Quality" of Roszdravnadzor
  - **Kusakabe T. -** Department of international cooperation of the Pharmaceuticals and Medical Devices Agency of Japan (PMDA)
  - **Radivojević B.** – medical devices Sector of the Agency for medicines and medical devices of Serbia

Representatives of regulatory authorities of India, Bangladesh, Peru, Kenya, Nigeria, the Gulf health Council, and the CIS countries are invited to participate

Hall 3
09.15-11.15
Round table
Issues of conducting clinical trials of medicines in the new epidemiological situation

Moderators: **Sharafetdinov A. Kh**. – Deputy Head of the Division of clinical trials of medicines of the Department for state regulation of medicine circulation of the Russian Ministry of Health, **Murzich T.V.** – the Deputy Head of Division clinical trials control of the Department of organization of state quality control of medical products of Roszdravnadzor, **Galeeva A.A.** – Director of clinical trials, medical and ethical issues of AIPM

- Adaptation of the process of conducting clinical trials in the context of the spread of coronavirus infection (**Sangonova D. F.** – member of the AIPM clinical trials Committee, BMS)
- The potential for process flexibility acquired during restrictions (**Vasiliev V. V.** – member of the AIPM clinical trials Committee, Roche)
- Experience in conducting COVID-19 clinical trials (**Semenova Yu., Klinkov A.** – members of the AIPM clinical trials Committee, Novartis)
- TransCelerate initiative, global experience gained during the COVID period (**Toporkov A. O.** – MSD)
- Exchange of opinions (in the format of a discussion with the participation of members of the AIPM clinical trials Committee **Dubrovina S. M.** – Pfizer, **Dontsenko A. B.** – GSK).
  Questions and answers

Hall 2
09.30-13.00
Session
Changes in the system of state quality control of medicines

Moderator: **Kosenko V.V.** – Deputy Head of Roszdravnadzor

- Regulatory innovations for entering of medicines into civil circulation. Results of state quality control of medicines in new realities (**Trapkova A. A.** – Acting Head Of the Department of state quality control of medical products of Roszdravnadzor)
- Quality control of medicines released under the accelerated procedure in conditions of threat of occurrence, occurrence and liquidation of an emergency (**Kosenko V. V.** – Deputy Head of Roszdravnadzor)
- Development of methods for rapid analysis of medicines (**Galeeva E. V.** – Head of the group of RAMAN spectroscopy and advanced developments of the Federal state budgetary institution "IMTSEUAOSMP" of Roszdravnadzor)
- Manufacturer's view on the new system for entering medicines into civil circulation (**Makarkina T. N.** – Quality Director of AstraZeneca industries LLC)
- 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)
- Development of regulatory and legal regulation of the EEC in the field of circulation of medicines (**Kravchuk A. M.** - Deputy Head of the Division 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)
- Pharmacopoeia regulation in the Eurasian economic Union: first edition of the Pharmacopoeia of the Union (**Nurashev T. B.** – Director Of the Department of technical regulation and accreditation of the Eurasian economic Commission)
- Creation of a unified information space for medicines within the EAEU (**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)

Hall 1
11.30-13.30
Medical devices export
With simultaneous translation

Moderators: **Astapenko E.M.** – Head of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor, **Revazyan G. A.** – Head of the Division of development of medical equipment and technology of the Department of radio-electronic industry of Ministry of Trade of Russia, **Sharikadze D.T**. - Director General of FGBU "VNIIIMT" of Roszdravnadzor

- Meeting domestic needs and developing exports of medical equipment in the post-covid era (**Revazyan G. A.** – Head of the Division of development of medical equipment and technology of the Department of radio-electronic industry of Ministry of Trade of Russia)
- Registration of medical devices. Market access in the country and in the region:
  - **Sasaki K.** – Deputy Director of the medical device evaluation Department of the Ministry of health, labor and welfare (MHLW) of Japan
  - **Ševaljević V.** – medical devices sector of the Medicines and Medical Devices Agency of Serbia (ALIMS)
  - **AlKhan A.** – engineer for registration of medical devices of the Center for registration of the Gulf health Council

  Representatives of regulatory authorities of India, Bangladesh, Peru, Kenya, and Nigeria are invited to participate
- SHVABE holding (Rostech Group): experience in bringing Russian medical devices to the foreign market, including using the RSDS digital platform and the ability to integrate regulators through the RSDS digital platform (**Ozhgikhin I. V.** – Deputy General Director for development of sales, marketing and service support systems for civil products of Shvabe Holding, **Pronin S.E.** – Executive Director of the Russian-Singapore Business Council)
- International cooperation, FGBU "VNIIIMT" of Roszdravnadzor in order to increase export potential of the country (**Fatkullina S. F.** – Head of the laboratory for work with biomodule of VNIIIMT of Roszdravnadzor)

Hall 3
11.30-13.30
Session
New aspects of medicines registration
Moderators: **Romanov F.A.** - Director of the Department of state regulation of medicines of the Ministry of Health of Russia, **Merkulov V. A.** – Deputy Director General of the FGBU "NTSESMP" of the Ministry of Health of Russia

Topiscs discussed:
- Features of the circulation of medicines in order to accelerate the introduction of medicines into the market, including for the prevention of new coronavirus infection
- Registration of medicinal products for medical use in the Eurasian economic Union
- Main mistakes of applicants when preparing registration dossiers in accordance with the Rules of registration and testing of medicines for medical use of the Eurasian economic Union

– Questions and answers. Exchange of views

Hall 1
14.00-16.00
Round table
Issues of development and production of medicinal reference standards
With simultaneous translation

Moderator: **Kosenko V.V.** – Deputy Head of Roszdravnadzor, **Romanov F.A.** - Director of the Department of state regulation of medicines of the Ministry of Health of Russia

– Organization of metrological service of the Ministry of health of Russia in the sphere of medicines circulation (**Romanov F.A.** - Director of the Department of state regulation of medicines of the Ministry of Health of Russia)
– Experience of foreign colleagues in the development and production of reference standards (**Lodi A.** – Head of the EDQM laboratory Department, **Pradeep O.** – senior Director, USP reference laboratory)
– Features of certification of reference standards of antibiotics (**Kuleshova S. I.** – Head of the laboratory of antibiotics of the Testing center for quality expertise of medicines of the FGBU "NTSESMP" of the Ministry of Health of Russia)
– Reference standards of immunobiological medicines (**Volkova R. A.** – Head of laboratory of molecular-biological and genetic methods of the Testing center for quality expertise of medicines of the FGBU "NTSESMP" of the Ministry of Health of Russia; **Fadeikina O. V.** – Chief technologist of the Center for quality expertise of medicines of the FGBU "NTSESMP" of the Ministry of Health of Russia)
– The modern practice of using reference standards for pharmaceutical analysis and ways of its improvement (**Chaplenko A. A.** – associate Professor of the Department of organization and management in the sphere of medicines circulation of the Sechenov University of the Ministry of Health of Russia)
– Reference standards of the EAEU Pharmacopoeia (**Tulegenova A. U.** – Head of the Scientific and educational Pharmacopoeia center of NAO Asfendiyarov Kazakh National Medical University, Chairman of the Pharmacopoeia Committee of the Eurasian economic Union)

Hall 2
14.00-18.15
Session
Pharmacovigilance and state control of clinical trials in the Russian Federation
Moderators: **Glagolev S. V.** – Adviser to the Minister of Health of the Russian Federation, **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, **Murzich T. V.** – Deputy Head of the Division of clinical trials control of the Department of state quality control of medical products of Roszdravnadzor

– Review of new requirements for conducting clinical trials in the EAEU (**Rozhdestvensky D.A.** - Head of the Department for Coordination of Works in the Field of Circulation of Medicines and Medical Devices of the Technical Regulation and Accreditation Department, Eurasian Economic Commission)
– Review of law enforcement practice of Roszdravnadzor on control of clinical trials (**Murzich T. V.** – Deputy Head of the Division of clinical trials control of the Department of state quality control of medical products of Roszdravnadzor)
– Organization of pharmacovigilance for medicines registered under the conditions (**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)
– Practical issues of implementing legislation in the field of pharmacovigilance – urgent and periodic reporting (**Polivanov V.A.** - Pharmacovigilance Center of the Federal State Budgetary Institution “IMTSEUAOSMP” of Roszdravnadzor)
– Draft requirements for inspection of pharmacovigilance systems for holders of registration certificates (**Setkina S. B.** - Deputy Head of the clinical and pharmacological laboratory of the Republican Unitary Enterprise "Center for Expertise and Testing in Health Care" of the Republic of Belarus)
– Practical experience of audits of pharmacovigilance systems of the holder of the registration certificates in the Republic of Kazakhstan (**Abdrakhmanov M. J.** – Head of Department for pharmacovigilance and monitoring the safety, efficacy and quality of medical devices of the Committee of Quality Control and safety of products and services of the Ministry of Health of the Republic of Kazakhstan)
– Risk management of generic medicines (**Matveev A.V.** – associate Professor of the Department of clinical pharmacology and therapy of FGBOU DPO RMANPO of the Russian Ministry of Health)
– The safety of the use of medicines in the treatment of COVID-19 in clinical practice (**Mirzaev K.B.** – associate Professor of clinical pharmacology and therapy of FGBOU DPO RMANPO of the Ministry of Health of Russia, Head of the division of personalized medicine of the Research Institute of Molecular and personalized medicine of the FGBOU DPO RMANPO of the Ministry of Health of Russia, the operating Director of the Information Center for pharmacotherapy for patients with new coronavirus infection COVID-19 “PharmaCOVID”)

Hall 3
14.00-16.00
Round table
Labeling of medical deevices

Moderators: **Merkulova E.E.** – Deputy Director of the Department of digital development and information technologies of the Ministry of Health of Russia, **Pavlyukov D. Yu.** – Deputy Head of Roszdravnadzor

- Experiment on labeling of medical devices in the territory of the Russian Federation: immediate prospects (**Migeeva M.A.** - Deputy Head of the Department for the Organization of State Control and Registration of Medical Devices of Roszdravnadzor)
- Features of labeling of different product groups. Prospects for labeling of medical devices (K**holkin S. I.** – Head of the pharmaceutical direction of LLC "Operator-CRPT»)
- On the course of the experiment on labeling wheelchairs with additional identification tools and monitoring their turnover in the Russian Federation (**Kostin A. A.**-General Director of the plant for the production of wheelchairs for the disabled, OTTO BOCK mobility LLC)
- Current issues of labeling of medical devices: the view of a foreign manufacturer (**Vanin S. Yu.** – Executive Director of the Association of international manufacturers of medical devices IMEDA)
- Experience in labeling of medical devices on the example of Medtronic (**Sapunova O.O.** - Head of the Registration and Product Quality Control Department of Medtronic LLC)

Hall 1
16.15-18.15
Session
State regulation of pricing for medicines and medical devices. Current requirements and ways of improvement

Moderators: **Pavlyukov D.Yu.** - Deputy Head of Roszdravnadzor, **Nizhegorodtsev T.V.** – Deputy Head of Antimonopoly Service of Russia, **Romanov F.A.** - Director of the Department of state regulation of medicines of the Ministry of Health of Russia, **Binko K.A.** - Deputy Director of the Department of Medicine Provision and Regulation of Medical Devices of the Ministry of Health of Russia

- Improving the system of state regulation of prices for medicines included in the list of vital and essential medicines (**Romanov F.A.** - Director of the Department of state regulation of medicines of the Ministry of Health of Russia)
- State regulation of prices for medical products (**Nizhegorodtsev T.V.** – Deputy Head of Antimonopoly Service of Russia)
- Organizational and economic aspects of improving drug provision for patients in the framework of the program of high-cost nosologies (**Maksimkina E.A.** - Director of the Department of Medicine Provision and Regulation of Medical Devices of the Ministry of Health of Russia)
- State regulation of prices for implantable medical devices (**Petrochenkov G.A.** - Acting Head of the Department of Control of the Implementation of State Programs in the Health Sector of Roszdravnadzor)
- The enforcement of the order of Ministry of Health of Russia from 15.05.2020 № 450N "On approval of the procedure for determining initial (maximum) contract price, price of the contract concluded with single supplier (contractor, performer), and the initial unit price of the goods, works, services when implementing purchases 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)
- Questions and answers. Exchange of views

Hall 3
16.15-18.15
Master class
How to correctly draw up a plan of corrective actions based on the results of control and supervisory measures in the field of medical device circulation

Moderators: **Astapenko E.M.** – 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 the Organization of State Control and Registration of Medical Devices of Roszdravnadzor

- The preparation of the program of corrective measures by results of carrying out supervisory activities (**Kudzhaev V. N.** – Head of Division of organization and conduct of state control of medical devices circulation of the Department of organization of state control and registration of medical devices of Roszdravnadzor)
- Preparation of a program of corrective actions in the event of an adverse event when using a medical device (**Anokhina E. V.** – Deputy Head of the Division of monitoring medical devices and keeping registers of the Department of organization of state control and registration of medical devices of Roszdravnadzor)
- Making changes to the documents of the registration dossier of a medical device during corrective actions (**Zhivlova O.V.** - Head of the Division for making changes in the registration documents of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor)

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