THE XX ANNIVERSARY ALL-RUSSIAN CONFERENCE «STATE REGULATION IN THE AREA OF MEDICINES AND MEDICAL DEVICES CIRCULATION» «PharmMedCirculation 2018»

PROGRAM

8–9 October 2018

Moscow Congress-Centre WTC

20th anniversary

ФАРММЕДОБРАЩЕНИЕ 2018

FEDERAL STATE BUDGETARY INSTITUTION
"CENTER FOR MONITORING AND CLINICAL AND ECONOMIC EXPERT EVALUATION"
OF FEDERAL SERVICE FOR SURVEILLANCE IN HEALTHCARE

SHORT PROGRAM

Schedule of events October 8

	Congress hall
09.00–13.00	**Plenary session** — *Modern regulatory system in the sphere of medicinal products circulation — global trends, challenges, opportunities*
	Congress hall 1
14.00–18.00	**Session** — *Digitalization in healthcare*
	Congress hall 2
14.00–18.00	**Round table** — *Improvement of the system of medical devices procurement for state and municipal needs. Regulation of prices for medical devices*
	Congress hall 3
14.00–18.00	**Session** — *Improvement of the medicines supply system in the Russian Federation. Improvement of the system of procurement of medicinal products for state and municipal needs*
	Amphitheater hall
14.00–18.00	**Session** — *The quality of medicines as one of the main components of ensuring the rights of citizens on quality medicinal care*
	Press hall
15.00–17.00	**Session** — *Actual issues of interaction between manufacturers of medical products and the media, the social responsibility of all stakeholders in the advertising of medicines and medical devices*

Schedule of events October 9

Congress hall 1	
09.00–13.00	**Session** — *The Russian pharmaceutical industry. Challenges and perspectives*
14.00–18.00	**Session** — *Track&Trace system (MDLP system). From experiment to full implementation*
Congress hall 2	
09.00–13.00	**Session** — *Modern requirements of the current legislation to the control and circulation of narcotic medicines and psychotropic substances and their precursors, the cultivation of narcotic plants on the territory of the Russian Federation. The structure of palliative care and the order of its organization in the Russian Federation*
14.00–18.00	**Session** — *Reform of control and supervisory activitiesin the Russian Federation. Actual issues of control and supervision of medicines*
Congress hall 3	
09.00–13.00	**Session** — *Registration of medical devices in the territory of the Russian Federation and within the framework of Eurasian Economic Union legislation*
14.00–18.00	**Session** — *Specifics of the state control of medical devices*
Amphitheater hall	
09.00–13.00	**Session** — *Expert evaluation and registration of pharmaceutical products*
14.00–18.00	**Session** — *Actual issues of state control of conducting medicines clinical trials in the Russian Federation and the EEU. Modern requirements for the organization and conduct of clinical trials*
Press hall	
14.00–18.00	**Round table** — *The problems of generating and distribution of pharmaceutical information*

October 8

October 8
09.00–13.00
Congress hall

Plenary session
With synchronous translation

Modern regulatory system in the sphere of medicinal products circulation — global trends, challenges, opportunities

Moderator: ***Protasov M.A.*** — Head of the Autonomous Non-commercial Organization "Russian quality system"

– Welcome address
  Ryazanskiy V.V. — Chairman of the Federation Council Committee on Social Policy
  Morozov D.A. — Chairman of the State Duma Committee for Health Protection
  Nazarenko V.V. — Minister for Technical Regulation of the Eurasian Economic Commission (EEC)
  Tsib S.A. — First Deputy Minister of Industry and Trade of the Russian Federation
  Venema J. — Executive Vice President and Chief Science Officer of the United States Pharmacopoeia Convention
– National project "Public Health" (***Kamkin E.G.*** — Deputy Minister of Health of the Russian Federation)
– Development of the regulatory system in the Russian Federation — current challenges and opportunities (***Murashko M.A.*** — Head of the Federal Service for Surveillance in Healthcare)
– Development of regulatory approaches to medicines provision in the Russian Federation (***Maksimkina E.A.*** — Director of the Department of Medicine Provision and Regulation of Medical Devices of the Ministry of Health of Russia)
– Establishment of regional centers of regulatory competences — a new regulatory paradigm (***Sillo H.*** — Group Lead, Country Regulatory Strengthening Regulatory Systems Strengthening Team, World Health Organization)
– Global regulatory convergence: cooperation and worksharing among regulators — pooling of resources and capabilities. Evolution of ICH — revision of approaches to global harmonization of requirements for the development and medicines approval. (***Dörr P.*** — Deputy Executive Director, Swissmedic, Switzerland)
– New approaches to in vitro & in vivo development and quality control of medicines in European countries (***Keitel S.*** — Director of the European Directorate for the Quality of Medicines and Health of the Council of Europe (EDQM))
– New approaches to the development and evaluation of medicinal products — the joint responsibility of the developer and regulator. Global programs of scientific and regulatory counseling, PRIME, Brakethrough (***Ausborn S.*** — Pharma Technical Regulatory, Regulatory Policy Lead EEMEA Pharma Technical Regulatory, Regulatory Policy Lead EEMEA)

October 8
14.00–18.00
Congress hall 1

Session

Digitalization in healthcare

Moderators: ***Panin A.I.*** — Adviser to the Head of Roszdravnadzor, ***Pospelov K.G.*** — Deputy Head of the Administration Department of the Federal Service for Surveillance in Healthcare

- Development of informatization in the healthcare system in the implementation of the Government Decree of the Russian Federation dated 05.05.2018 № 555 "Unified information system in healthcare". Use of the Information and Analytical System (IAS) for monitoring and control in state procurement of medicines (***Boyko E.L.*** — Director of the Department of Digital Development and Information Technologies of the Ministry of Health of the Russian Federation)
- IT in pharmaceutics (***Samsonov M.Yu.*** — Director of the Medical Department of JSC "R-Pharm", ***Pochkaev E.A.*** — Vice-President of CJSC "Biocad")
- IT in pharmaceutics and medical equipment manufacturing (***Elinson A.M.*** — General Director of NMC "Electron")
- Information system of patients with implanted medical devices. Cardiovascular register of patients (***Valeeva A.A.*** — Deputy Head of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor
- Use of MedDRA international terminology in pharmacovigilance (***Glagolev S.V.*** — Deputy Head of the Department — Head of the Division of Organization of Pharmacovigilance of the Department of Organization of State Control of the Quality of Medical Products of Roszdravnadzor)
- Application of digital technologies in the framework of the reform of control and supervision activities (***Kachanov O.Yu.*** — Director of the Department of Informatization Projects of the Ministry of Digital Development, Communication and Mass Communications of the Russian Federation)
- The Eurasian Economic Union (EEU) information system: principles of organization and work within a single market (***Rozhdestvensky D.A.*** — Head of the Coordination division for Medicines and Medical Devices of the Department of Technical Regulation and Accreditation of the Eurasian Economic Commission (EEC))
- Application of information technologies to improve control, supervisory and licensing activities within the framework of the reform of the control and supervisory activity (***Pospelov K.G.*** — Deputy Head of the Administration Department of Roszdravnadzor)
- Practical application of information technologies for the implementation of special public services (***Pribezhishaya G.N.*** — the Head of Roszdravnadzor territorial body for Krasnodar region)
- Quality control of medical devices (***Menshikova G.I.*** — Head of the Department of the territorial body of Roszdravnadzor in Tver region)
- Application of the Roszdravnadzor information system in the implementation of state quality control of medicines and monitoring of medicines quality (***Fedoseeva O.B.*** — Head of the territorial body of Roszdravnadzor in Sverdlovsk region)
- Application of Roszdravnadzor's "open data" in the business (***Denisova M.N.*** — Director of Operations iQVIA)
- Questions and answers. Opinion exchange

October 8
14.00–18.00
Congress hall 2

Round table

Improvement of the system of medical devices procurement for state and municipal needs. Regulation of prices for medical devices (with the participation of representatives of the Ministry of Health of Russia, the Ministry of Economic Development of Russia, the Ministry of Industry and Trade of Russia, the Ministry of Finance of Russia, the Ministry of Labor of Russia, Federal Antimonopoly Service of the Russian Federation, Social Insurance Fund, FRP)

Moderators: ***Pavlyukov D.Yu.*** — Deputy Head of Roszdravnadzor, ***Astapenko E.M.*** — Head of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor, ***Ivanov I.V.*** — General Director of the Federal State Budgetary Institution the "Center of Monitoring and Clinical Economic Expertise" (FGBU "TsMIKEE") of Roszdravnadzor

– Formation features and prospects for the application of the catalog of medical devices (***Tsybulskaya V.I.*** — Head of the Department of Information Support in the Sphere of Procurement of the Ministry of Finance of Russia)
– Restrictions and conditions for admission of certain types of medical devices to the Russian market during procurement (***Alekhin A.V.*** — Director of the Department for the Development of the Pharmaceutical and Medical Industry of the Ministry of Industry and Trade of the Russian Federation)
– State regulation of prices for implantable medical devices (***Fisenko V.S.*** — Head of the Department for Control over the Implementation of State Programs of Roszdravnadzor)
– Questions and answers. Opinion exchange

October 8
14.00–18.00
Congress-hall 3

Session

Improvement of the medicines supply system in the Russian Federation. Improvement of the system of procurement of medicinal products for state and municipal needs

Moderators: ***Maksimkina E.A.*** — Director of the Department of Medicine Provision and Regulation of Medical Devices of the Ministry of Health of Russia, ***Fisenko V.S.*** — Head of the Department for Control over the Implementation of State Programs of Roszdravnadzor

- Improvement of the medicines provision system in the Russian Federation (***Maksimkina E.A.*** — Director of the Department of Medicine Provision and Regulation of Medical Devices of the Ministry of Health of Russia)
- Control over the implementation of programs of subsidized medicines provision (***Fisenko V.S.*** — Head of the Department for Control over the Implementation of State Programs of Roszdravnadzor)
- Information and analytical system for monitoring and control in the procurement of medicines as a mean to increase the efficiency of spending budget funds (***Konstantinova O.A.*** — Deputy Director of the Department of Medicine Provision and Regulation of Medical Devices of the Ministry of Health of Russia)
- Information support and control in the state procurement system (***Demidov E.G.*** — Deputy Head of the Department for the Development of the Contract System of the Federal Treasury)
- The status of works on the development of the information and analytical system for monitoring and control in the procurement of medicinal products for state and municipal needs (***Serebryakov V.Yu.*** — General Director of LLC "NCEM" (Rostekh SC))
- Ensuring competition in the procurement of medicines for state and municipal needs (***Nijegorodcev T.V.*** — Deputy Head of the Department of Control of Social Sphere and Trade of the FAS Russia)

October 8
14.00–18.00
Amphitheater hall

Session
With synchronous translation

The quality of medicines as one of the main components of ensuring the rights of citizens on quality medicinal care

Moderators: ***Kosenko V.V.*** — Deputy Head of Roszdravnadzor, ***Keitel S.*** — Director of the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe (EDQM)

- Approaches to the standardization of the quality of medicines in the framework of the State Pharmacopoeia of the Russian Federation and the Pharmacopoeia of the EEU (Eurasian Economic Union) (***Sakanyan E.I.*** — Chairman of the EEU Pharmacopeia Committee)
- EU Official Control Authority Batch Release (OCABR) for Human Biologicals (***Keitel S.*** — Director of the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe (EDQM))
- New approaches in the development of quality standards for biologics (***Venema J.*** — Executive Vice President and Chief Science Officer of the United States Pharmacopoeia Convention)
- Development of quality standards for over-the-counter or non-prescription medicines (***Venema J.*** — Executive Vice President and Chief Science Officer of the United States Pharmacopoeia Convention)
- The approach of flexibility and the possibility of its application in the EEU Pharmacopoeia (***Tulegenova A.U.*** — Deputy Chairman of the EEU Pharmacopoeia Committee, Head of the Center for the Improvement of the State Pharmacopoeia of the Republic of Kazakhstan and the Pharmacopoeia of the EEU RGP on PHV "National Center for Expertise of Medicines, Medical Devices and Medical Equipment" of the Ministry of Health of the Republic of Kazakhstan)
- Changing approaches to state quality control of medicines in the Russian Federation (***Kosenko V.V.*** — Deputy Head of Roszdravnadzor)
- Interaction of Roszdravnadzor with law enforcement agencies to stop circulation of counterfeit medical products (***Plutnitsky A.N.*** — Head of the Roszdravnadzor territorial body for Moscow and Moscow region)
- USP's Engagement in Excipient Quality: Overview of the Importance of Excipient Monographs (***Moore K.*** — Senior Manager, of the United States Pharmacopoeia Convention)
- Features of production and quality control of radiopharmaceuticals. Problems and solutions (***Zelinskaya E.V.*** — GMP-expert of IBA RadioPharma Solutions)

Actual issues of interaction between manufacturers of medical products and the media, the social responsibility of all stakeholders in the advertising of medicines and medical devices

October 8
15.00–17.00
Press hall

Session

Moderator: ***Maleva O.Yu.*** — Adviser to the Head of Roszdravnadzor

- Informing the media about the production of domestic medicines and medical devices in the conditions of import substitution (***Buzin V.N.*** — Director of the Department of Public Health and Communications of the Ministry of Health of Russia)
- Review of the advertising market for medical products. Specificity and requirements for advertising of medical products (***Ivliev D.A.*** — Deputy Director of Commercial Directorate of JSC "First Channel")
- Compliance with the antimonopoly legislation in advertising medical products (***Nikitina T.E.*** — Head of the Department of Control of Advertising and Unfair Competition of the Federal Antimonopoly Service (FAS) of Russia)
- Social responsibility of manufacturers of medical products to consumers of medicines and medical devices when creating and distributing advertisements in the media (***Zhulyov Yu.A.*** — Co-chairman of the All-Russian Patient Union, ***Glushkov I.A.*** — Deputy Director General of STADA CIS)
- Legal restrictions and opportunities for promotion of medical products on the market (***Grits D.S.*** — Director of the Institute of Business Law of University named after Kutafin O.E.)
- Educational activity of Roszdravnadzor in the field of patient law knowledge and creation of audiovisual training applications for the medical community (***Akhvlediani M.V.*** — Press Service of Roszdravnadzor)

October 9

October 9
09.00–13.00
Congress hall 1

Session

The Russian pharmaceutical industry. Challenges and perspectives

Moderators: ***Kosenko V.V.*** — Deputy Head of Roszdravnadzor, ***Denisova E.V.*** — Deputy Director of the Department of Development of Pharmaceutical and Medical Industry the Ministry of Industry and Trade of the Russian Federation

- Strategy PHARMA-2030 (***Denisova E.V.*** — Deputy Director of the Department of Development of Pharmaceutical and Medical Industry the Ministry of Industry and Trade of the Russian Federation)
- State support of Russian medicine manufacturers. Preferences in the manufacture of pharmaceuticals from domestic pharmaceutical substances (***Denisova E.V.*** — Deputy Director of the Department of Development of Pharmaceutical and Medical Industry the Ministry of Industry and Trade of the Russian Federation)
- The regulator's key role in the PHARMA-2030 strategy (***Chagin D.A.*** — Chairman of the Board of the Association of Pharmaceutical Manufacturers of the EEU)
- Export opportunities of Russian medicines (***Torgov A.V.*** — Deputy General Director for work with authorities of "Biocad")
- The approach to registration of pharmaceutical products with the conditions, as a mechanism of innovative development of the pharmaceutical industry and non-monetary support of the development of domestic manufacturers (***Galkin D.S.*** — Director for Relations with the State Authorities and for Legal Issues of the state corporation "HimRar")
- Development of the pharmaceutical industry for the period until 2030 — the relationship with the priorities of the health care system of the Russian Federation (***Shipkov V.G.*** — Executive Director of the Association of International Pharmaceutical Manufacturers)
- Introduction of a risk-oriented approach to the control of pharmaceutical companies by Roszdravnadzor (***Trapkova A.A.*** — Acting Head of the Department of the Organization of State Quality Control of Medical Products of Roszdravnadzor)
- The results of inspection of foreign medicine manufacturers for compliance with the good manufacturing organization and medicines quality control practices. Analysis of detected inconsistencies (***Shestakov V.N.*** — Director of the State Institute for Medicines and Good Practices (FBU "GILSiNP") of the Ministry of Industry and Trade of the Russian Federation)
- Issues of the import of pharmaceutical substances into the territory of the Russian Federation (representative of the Federal Customs Service)

October 9
09.00–13.00
Congress-hall 2

Session

Modern requirements of the current legislation to the control and circulation of narcotic medicines and psychotropic substances and their precursors, the cultivation of narcotic plants on the territory of the Russian Federation. The structure of palliative care and the order of its organization in the Russian Federation

Moderators: ***Semecheva S.V.*** — Deputy Director of the Department of Medicine Provisioin and Regulation of Medical Devices of the Ministry of Health of Russia, ***Krupnova I.V.*** — Head of the Department for Licensing and Compliance Control of Roszdravnadzor

- Legal regulation in the sphere of circulation of narcotic medicines and psychotropic substances and their precursors, cultivation of narcotic plants, harmonization of normative legal acts of the Russian Federation with universally recognized principles and norms of international law in the field of combating illicit narcotics and their precursors trafficking (***Panova O.S.*** — Head of the Division of Legal Regulation of Pharmaceutical Activity, Traffic of Narcotic Medicines and Psychotropic Substances of the Department of Medicinal Provision and Regulation of Medical Devices of the Ministry of Health of the Russian Federation)
- Peculiarities of prevention and investigation of crimes committed in the sphere of legal circulation of narcotic medicines and psychotropic substances and their precursors (***Khrapov A.I.*** — Head of the Chief Department for Drug Control of the Ministry of Internal Affairs of the Russian Federation)
- Modern forms of control and supervision in the sphere of circulation of narcotic medicines and psychotropic substances and their precursors (***Polinskaya T.A.*** — Head of territorial body of Roszdravnadzor for the Rostov region)
- Features of licensing of activities related to narcotic medicines and psychotropic substances and their precursors, cultivation of narcotic plants (***Orihivskaya E.N.*** — Head of the Department of licensing and accreditation of the Department of Healthcare of Moscow)
- The structure of palliative care and the order of its organization in the Russian Federation. Problems and solutions. Study of the best practices, modern approaches in the field of narcotic medicines provision for oncological patients for pain treatment (***Nevzorova D.V.*** — chief external expert of the Ministry of Health of Russia, ***Pshonkin A.V.*** — Head of the in-patient hospital for short-term treatment of the National Medical Research Center for Pediatric Hematology, Oncology and Immunology (FGBU FNKTS DGOI) named after Rogachev, assistant of the Department of palliative pediatrics and laser medicine of the Russian National Research Medical University (RNRMU) named after Pirogov)
- Implementation of the action plan (“road map”) “Increasing the availability of narcotic medicines and psychotropic substances for medical use” (***Cherkasov D.I.*** — Adviser to the Director of Federal State Unitary Enterprise “Moscow Endocrine Factory”)

– Counteraction to "pharmacy drug addiction" and organization of law enforcement authorities cooperation (***Chebotareva N.I.*** — Head of the Department for Medicines Control of the territorial body of Roszdravnadzor in Moscow and the Moscow region)
– Pharmacy organizations: issues of handling narcotic medicines and psychotropic substances, practical solutions (***Chernysheva G.Yu.*** — General Director of OJSC "Amurfarmatsiya")

Registration of medical devices in the territory of the Russian Federation and within the framework of Eurasian Economic Union legislation

October 9
09.00–13.00
Congress hall 3

Session

Moderators: ***Astapenko E.M.*** — Head of the Department of Organization of State Control and Registration of Medical Devices 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, ***Ivanov I.V.*** — General Director of the FGBU "Center of Monitoring and Clinical Economic Expertise" (FGBU "TsMIKEE") of Roszdravnadzor

- Novels of legal regulation in the sphere of medical devices circulation (***Astapenko E.M.*** — Head of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor)
- The procedure for introducing changes in the registration documents for a medical device (***Zhivlova O.V.***— Head of the Department for introducing changes in the registration documents of Roszdravnadzor)
- General requirements for the safety and efficacy of medical devices as the basis for the circulation of medical devices on the territory of the Eurasian Economic Union (***Antonov V.S.*** — Assistant to the Director General of the FGBU "TsMIKEE" of Roszdravnadzor)
- The procedure for conducting technical tests and studies to assess the biological effect of medical devices (***Nikiforova L.Yu.*** — Head of the Expertise Department of the Federal State Budgetary Institution the All-Russian Scientific Research and Test Institute of Medical Equipment (FGBU "VNIIIMT") of Roszdravnadzor)
- Specifics of carrying out clinical trials of medical devices for registration within the framework of the Eurasian Economic Union (***Valeeva A.A.*** — Deputy Head of the Department for Organization of State Control and Registration of Medical Devices of Roszdravnadzor)
- Procedure for registration of medical devices within the framework of the Eurasian Economic Union (***Abdimanova B.Zh.*** — Managing Director of the Republican State Enterprise on the right of economic management "National Center for Expertise of Medicines, Medical Devices and Medical Equipment" of the Ministry of Health of the Republic of Kazakhstan)
- Inspection of the production of medical devices. Requirements for the introduction, maintenance and evaluation of the quality management system for medical devices, depending on the potential risk of their use (***Akhtyamov E.I.*** — Deputy Head of Licensing and Compliance Control Department of Roszdravnadzor)
- Experience of implementi ng the quality management system with the example of JSC "MTL" (***Bobrov V.A.***— Deputy General Director of JSC "MTL")
- Questions and answers. Opinion exchange

October 9
09.00–13.00
Amphitheater hall

Session

Expert evaluation and registration of pharmaceutical products

Moderators: ***Romanov F.A.*** — Director of the Department of state regulation of medicines of the Ministry of Health of Russia, ***Olefir Yu.V.*** — Director General of the "Scientific Centre for Expert Evaluation of Medicinal Products" (FGBU "NTSESMP") of the Ministry of Health of Russia

- Improvement of legal regulation in the field of medicinal products in the Russian Federation (***Romanov F.A.*** — Director of the Department of State Regulation of Medicines of the Ministry of Health of Russia)
- Expert evaluation of medicines quality (***Kovaleva E.L.*** — Deputy Director of the Center for Expertise and Control of Finished Medicinal Products (FMP) of FGBU "NTSESMP" of the Ministry of Health of Russia, ***Luttseva A.I.*** — Head of the Medicines Test Center of the FGBU "NTSESMP" of the Ministry of Health of Russia)
- General issues of clinical trials. Regulatory requirements for different types of clinical trials (***Goryachev D.V.*** — Director of the Center for Expertise and Control of Finished Medicinal Products of the FGBU "NTSESMP" of the Ministry of Health of Russia)
- Safety issues of biotherapeutic medicines (therapeutic proteins) associated with the their immunogenicity (***Avdeeva Zh.I.*** — the chief expert of the Department of Expertise of Allergens, Cytokines and other immunomodulators of the Center for Expertise and Control of Medical Immunobiological Preparations of the FGBU "NTSESMP" of the Ministry of Health of Russia)
- Submission of information in the instructions for the medical use of the medicinal product within the registration procedure in the Russian Federation (***Parfenova E.Yu.*** — expert of the 1st category of the Department No. 1 for the efficacy and safety of the medicines of the Center for Expertise and Control of FM P of the FGBU "NTSESMP" of the Ministry of Health of Russia)
- New requirements for assessing the safety of biotechnological medicines (***Soldatov A.A.*** — the chief expert of the Department of Expertise of Allergens, Cytokines and other immunomodulators of the Center for Expertise and Control of Medical Immunobiological Preparations of the FGBU "NTSESMP" of the Ministry of Health of the Russia)
- Bioequivalence testing during registration of medicinal products (***Eremenko N.N.*** — chief expert of the Department No. 1 for medicines efficacy and safety of the Center for Expertise and Control of FMP of the FGBU "NTSESMP" of the Ministry of Health of Russia)
- Expert approaches to assessing the relationship between the expected benefit and the possible risks of medicines application in pediatrics (***Solovieva A.P.*** — chief expert of the Department No. 2 on the efficacy and safety of medicines of the Center for Expertise and Control of FMP of the FGBU "NTSESMP" of the Ministry of Health of Russia)
- Digitization of regulatory procedures as an effective format for maintaining the regulatory cycle of the pharmaceutical product. A new format for the interaction of the regulator and the applicant with the example of eCTD (***Burger M.*** — Head of the global unit for the preparation of the dossier of Novartis)

October 9
14.00–18.00
Congress hall 1

Session

Track&Trace system (MDLP system). From experiment to full implementation

Moderators: ***Kosenko V.V.*** — Deputy Head of Roszdravnadzor, ***Dubin M.A.*** — Chairman of the Board of Directors of the Center for Development of Perspective Technologies (CRPT)

- Regulatory and legal framework for the implementation of the Track&Trace system (***Kosenko V.V.*** — Deputy Head of Roszdravnadzor)
- Actual status and results of the medicines marking experiment (***Maltsev V.G.*** — Deputy Head of the Department for Control of Goods Circulation of the Federal Tax Service of Russia)
- Progress of implementation and directions of the development of the marking system (***Kharitonov A.Y.*** — Head of the Goods Direction "Pharma" of the Center for Development of Perspective Technologies ("CRPT"))
- Features of the implemented Track&Trace system and challenges faced by the manufacturers (***Belov E.B.*** — Head of the Department of technological projects at Bayer on behalf of the Track&Trace Working Group of the Association of International Pharmaceutical Manufacturers)
- Proposals for practical steps to optimize the implementation of Track&Trace system at manufacturing (***Mustafina M.R.*** — a group of companies Novartis on behalf of the Track&Trace Working Group of the Association of International Pharmaceutical Manufacturers)
- Track&Trace system. The view of the pharmaceutical manufacturer (***Timokhin S.V.*** — Technical Director of LLC "AstraZeneca Industries")
- Experience in implementing the Track&Trace system in the Russian pharmaceutical industry (***Akhantiev A.R.*** — LLC "Geropharm", ***Bykov A.V.*** — JSC "R-Pharm")
- Experience in implementing the Track&Trace system in a wholesale organization (***Galyamova V.V.*** — Executive Director of JSC NPK "Katren")
- Experience in implementing the Track&Trace system in the retail organization (***Nefantyev E.O.*** — General Director of LLC "NEO-PHARM")
- Application of information registers of the Ministry of Health of Russia in the medicines marking system (***Merkulova E.E.*** — Head of the coordination of regional informatization programs in healthcare of the Department of Information Technologies and Communication of the Ministry of Health of Russia)
- Realization of the traceability project for foreign marketing authorization holders and importers (***Bagley D.Yu.*** — Business processes expert)
- General discussion

October 9
14.00–18.00
Congress hall 2

Session

Reform of control and supervisory activitiesin the Russian Federation. Actual issues of control and supervision of medicines

Moderators: ***Semecheva S.V.*** — Deputy Director of the Department of Medicine Provision and Regulation of Medical Devices of the Ministry of Health of Russia, ***Parkhomenko D.V.*** — Deputy Head of Roszdravnadzor, ***Krupnova I.V.*** — Head of the Department for Licensing and Compliance Control of Roszdravnadzor

– Reform of control and supervision activities:
  - Implementation of a risk-oriented approach in Roszdravnadzor's control and supervisory activities, the first results of planning and conducting routine inspections (***Krupnova I.V.*** — Head of the Department for Licensing and Compliance Control of Roszdravnadzor, ***Guskova I.A.*** — Deputy Head of the Department for Licensing and Compliance Control of Roszdravnadzor)
  - Systematization, reduction in the number and updating of mandatory requirements for controlled types of health care activities (***Starostina I.S.*** — Head of the Division of Medicines Control of the Department for Licensing and Compliance Control of Roszdravnadzor)
  - Introduction of a system of comprehensive prevention of mandatory requirements violations for legal entities and individual entrepreneurs engaged in health care (medical activities, medicines and medical devices sales) (***Krupnova I.V.*** — Head of the Department for Licensing and Compliance Control of Roszdravnadzor, ***Starostina I.S.*** — Head of the Division of Medicines Control of the Department for Licensing and Compliance Control of Roszdravnadzor)
– Evaluation of the regulatory impact of certain regulatory legal documents on the activities of pharmaceutical organizations (***Nevolina E.V.*** — executive director of the NP "Pharmacy Guild" and the Union "National Pharmaceutical Chamber")
– Practical implementation of good practices. Problems of implementation and what needs to be changed in regulations for pharmaceutical activity (***Gladkova E.V.*** — President of the Samara Regional Pharmaceutical Association)
– Modern approaches to the education of pharmaceutical workers (***Kosova I.V.*** — Head of the Department of Management and Marketing of Pharmacy FPK MR RUDN)
– Implementation of a comprehensive prevention system for violations of mandatory requirements by the territorial body of Roszdravnadzor for Moscow and the Moscow Region (***Chebotareva N.I.*** — Head of the Department for Medicines Control of the territorial body of Roszdravnadzor in Moscow and the Moscow Region)
– Formation of healthy competition in the pharmaceutical market (***Titova L.V.*** — Executive Director of the SPFO)

October 9
14.00–18.00
Congress hall 3

Session

Specifics of the state control of medical devices

Moderators: ***Pavlyukov D.Yu.*** — Deputy Head of Roszdravnadzor, ***Astapenko E.M.*** — Head of the Department of organization of state control and registration of medical devices of Roszdravnadzor, ***Sharikadze D.T.*** — General Director of the Federal State Budgetary Institution the "All-Russian Scientific Research and Test Institute of Medical Equipment" (FGBU "VNIIIMT") of Roszdravnadzor

- Actual issues of organization of control and supervisory activities in the sphere of medical devices in the light of the risk-oriented approach (***Migeeva M.A.*** — Deputy Head of the Department of Organization of State Control and Registration of Medical Devices of Roszdravnadzor)
- The practice of applying checklists in control and supervision of medical devices (***Dorofeev A.A.*** — Head of the Department of Organization and Conducting State Control of Medical Devices of Roszdravnadzor)
- Typical violations detected during the examination of quality, efficacy and safety of medical devices (***Nikiforova L.Yu.*** — Head of the Expertise Department of the FGBU "VNIIIMT" of Roszdravnadzor)
- Cooperation experience between Roszdravnadzor and law enforcement agencies in conducting control and surveillance of medical devices (***Plutnitsky A.N.*** — Head of the territorial body of Roszdravnadzor in Moscow and Moscow region)
- Status of the Russian market of industrial sterilization. Influence of the sterilization method on the final quality of a medical device (***Mishin D.A.*** — General Director of LLC "Gazsteryl")
- Labeling of medical devices. International experience (***Krotkov A.A.*** — leading expert of GS1 Russia)
- Questions and answers. Opinion exchange

October 9
14.00–18.00
Amphitheater hall

Session

Actual issues of state control of conducting medicines clinical trials in the Russian Federation and the EEU. Modern requirements for the organization and conduct of clinical trials

Moderators: ***Romanov B.K.*** — Deputy Director General of the Scientific Centre for Expert Evaluation of Medicinal Products (FGBU "NTSESMP") of the Ministry of Health of Russia, ***Vrubel M.E.*** — Deputy Head of the Division of Clinical Trials Control of the Department of Organization the State Quality Control of Medical Products of Roszdravnadzor

- Clinical trials in the EEU: regulatory approaches and requirements for the scope of trials (***Rozhdestvensky D.A.*** — Head of the Coordination division for Medicines and Medical Devices of the Department of Technical Regulation and Accreditation of the Eurasian Economic Commission (EEC))
- General requirements to safety materials for clinical trials (***Romanov B.K.*** — Deputy Director General of FGBU "NTSESMP" of the Ministry of Health of Russia)
- Review of law enforcement practice in monitoring clinical trials in the Russian Federation. Realization of the risk-oriented approach in control and supervisory activities of Roszdravnadzor (***Vrubel M.E.*** — Deputy Head of the Division of Clinical Trials Control of the Department of Organization the State Quality Control of Medical Products of Roszdravnadzor)
- Rules for the conduction of clinical trials in the European Union. New aspects of regulation in the European Union (***Karpova N.*** — senior expert of the Department of Registration of Medicines, EMA CHMP)
- Biosimilars: a systematic review of randomized controlled trials and observational programs (***Almer A.*** — Head of Biotherapeutic medicines and Immunological Diseases in Eastern Europe, Middle East and Africa, EEMEA)
- Issues of providing good practices in the development and research of biotechnological medicines (***Poteryaev D.A.*** — Deputy General Director for Science of LLC "MBC Generium")

The problems of generating and distribution of pharmaceutical information

October 9
14.00–18.00
Press-hall

Round table

Moderator: ***Yagudina R.I.*** — Head of Department of Organization of Medicines Provision and Pharmacoeconomics of the First Moscow State Medical University named after Sechenov (Sechenov's University)

- Mechanisms and sources of the formation of pharmaceutical information. Problems of bringing pharmaceutical information to medical and pharmaceutical workers (***Yagudina R.I.*** — Head of Department of Organization of Medicines Provision and Pharmacoeconomics of the First Moscow State Medical University named after Sechenov (Sechenov's University))
- Quality of medicines instructions for physicians and people: the results of a European study (***Volskaya E.A.*** — Vice-Rector for Scientific Work at Moscow State University of Medicine and Stomatology named after Evdokimov A.I.)
- Instruction for use of medicines as the most mass source of information for health care professionals and the public (***Logvinyuk P.A.*** — lecturer of the Department of Organization of Medicines Provision and Pharmacoeconomics of the First Moscow State Medical University named after Sechenov (Sechenov's University))
- Opportunities of medicine manufacturers in the formation and delivery of pharmaceutical information to health professionals (***Osokin A.G.*** — Head of Pharmacovigilance and Medical Communications of GSK (GlaxoSmithKline) Pharma)
- The problems of bringing pharmaceutical information from the point of view of professional ethics and pharmaceutical marketing (***Khristich M.N.*** — an expert of the Moscow Pharmaceutical Society, a member of Russian Association of Pharmaceutical Marketing (RAPM))

Please note that the Organizing Committee reserves the right to make changes in the program and in the list of speakers