XVI All-Russian Conference «State regulation in the field of medicines and medical devices circulation»

PROGRAM

10 years of Federal service on surveillance in healthcare

29-30 October 2014

Moscow
Tourist hotel complex «Izmailovo»

ФАРММЕДОБРАЩЕНИЕ 2014

10 years of Federal service on surveillance in healthcare

Dear participants and guests, distinguished colleagues!

The face of modern health care is largely determined by the wide scale introduction of advanced methods of disease diagnostics and treatment, use of cutting edge medical technology, innovative drugs and medical devices. Role of modern biotechnology, new dosage forms and delivery systems is continuously increasing. New and updated medical products, better and more efficient means of diagnosis and treatment are constantly coming to the market. New control systemsforcirculation of medical products in the supply chain, rapidly developing mechanisms for international regulatory interactionand interagency cooperation had been introduced. A hallmark of ourtime is a society'sattention to the regulatory agencies efforts, as well as increased demands on the quality of their work aimed at ensuring the availability, quality and safety of medical products and health care.

These issues will be addressed in the course of Roszdravnadzor XVIAll-Russian Conference «State regulation in the field of medicines and medical devices circulation — FarmMedObraschenie 2014».

I am sure that all constructive ideas and suggestions of the participants will be requiredtoachieve our main common objective — providing consumers and healthcarewith quality, safe and effective medical products.

I wish all the participants and guests of the Conference a productive and fruitful work!

Sincerely,
Acting head of Roszdravnadzor ***Murashko M.A.***

29 October 2014

MCH «Izmailovo»

9.30–12.00	**Plenary session**
13.00–18.00	**Breakout session** *State quality control for medicines: focus on quality and development outlook*

«Gamma-Delta» Building, «Moscow 1» Hall

13.00–16.00	**Breakout session** *Manufacturing of medicines. New development trends.*
16.15–18.30	**Breakout session** *The role of the logistics system in ensuring the quality and accessibility of medicines and medical devices*

«Gamma-Delta» Building, «Moscow 2» Hall

13.00–18.00	**Breakout session** *Ensuring availability of pharmaceutical care*

«Gamma-Delta» Building, «Rostov» Hall

13.00–15.00	**Breakout session** *Medicines and medical products circulation in the Customs Union and the Eurasian Economic Community. New ways of effective cooperation*

SHORT PROGRAM

10 years ROSZDRAVNADZOR

30 October 2014

	MCH «Izmailovo»
9.00–15.00	**Breakout session** *Expert evaluation and registration of medications. Challenges and Solutions*
15.15–18.30	**Breakout Session** *Biotech drugs — global trends of global development*
	«Gamma-Delta» Building, «Moscow 1» Hall
9.00–12.00	**Breakout Session** *Good manufacturing practices: steps toward success*
13.00–16.00	**Breakout Session** *Current issues of drug safety monitoring: «sore spots» and what could be done*
	«Gamma-Delta» Building, «Moscow 2» Hall
9.00–12.00	**Breakout Session** *Licensing of pharmaceutical activity as a key quality performance indicator*
13.00–16.00	**Breakout Session** *Pharmacy medicines compounding. Legislation and reality*
	«Gamma-Delta» Building, «Rostov» Hall
9.00–12.00	**Breakout Session** *Registration of medical devices: legal regulation and current issues*
13.00–17.00	**Breakout Session** *Special aspects of registration of medical devices for in vitro diagnostic*

«Gamma-Delta» Building, «Vladimir» Hall

9.00–15.30 **Breakout Session**
Proper conduct of clinical studies. What is good and what is bad?

«Gamma-Delta» Building, «Suzdal» Hall

13.00–17.00 **Breakout Session**
Registration of certain types of medical devices

10 years ROSZDRAVNADZOR

29 October

29 October
9.30–12.00
MCH «Izmailovo»

Plenary session
with simultaneous English translation

– Opening address (***Skvortsova V.I.*** — Minister of Healthcare of the Russian Federation)
– State control and compliance monitoring in medicines and medical devices circulation. Potential, realities, outlook (***Murashko M.A.*** — Acting Head of Roszdravnadzor)
– Legal provisions for medicines and medical devices circulation control. Current objectives of the legislative authorities (***Kalashnikov S.V.*** — Chairman of State Duma's Committee on Healthcare)
– Strategy of the drug provision for the Russian Federation population until 2025. Preliminary results of Stage I (***Maksimkina E.A.*** — Director of the Division for medicine provision and medical products regulation, Russian Ministry of Health)
– Progress in the implementation of «Pharma 2020» Strategy (***Tsyb S.A.*** — Deputy Minister of Industry and Trade of the Russian Federation)
– Regulation of medical products circulation in the framework of the Eurasian Economic Community. Adapting to new realities (***Boitsov V.B.*** — Director of the Department for Technical Regulation and Accreditation by the Eurasian Economic Commission.
– Current approach to the quality of medicines. EU's focus (***Keitel S.*** — Director of the European Directorate for the Quality of Medicines and Healthcare (EDQM))
– Adapting Serbian legislation to the European standards of medical products circulation (***Jacovic S.*** — Director of the Agency for Medicines and Medical Devices of the Republic of Serbia (ALIMS))

29 October
13.00–18.00
MCH «Izmailovo»

Breakout session
with simultaneous
English translation

State quality control for medicines: focus on quality and development outlook

Co-chairs: ***Kosenko V.V.*** — Head of the Division of organization of state quality control of medical products of Roszdravnadzor, ***Keitel S.*** — Director of the European Directorate for the Quality of Medicines and Healthcare (EDQM), ***Piervincenzi R.*** — director of the United States Pharmacopoeia Convention

- Russian Federation State system of pharmaceuticals quality control. Current issues and development perspectives (***Kosenko V.V*** — Head of the Division of of state quality control of medical products Roszdravnadzor)
- Risk profiles for medicines imported into the Russian Federation (***Ryazanov A.I*** — Deputy Head of the Department of trade restrictions, currency and export control of the Federal Customs Service)
- Strategic development of the European Pharmacopoeia. Pharmacopeia harmonization (***Keitel S.*** — Director of the European Directorate for the Quality of Medicines and Healthcare (EDQM))
- USP strategic objectives. Global pharmacopeia harmonization (***Piervinchentsi R.*** — Executive Director of the United States Pharmacopoeia Convention)
- Indian Pharmacopoeia. Pharmacopeia harmonization (***G.N. Singh*** — Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, and Drug Controller
- Republic of Kazakhstan State Pharmacopoeia as an instrument of medicines State quality control. Challenges and solutions (***Tulegenova A.U.*** — Director of the Pharmacopoeia Center, National Center of expertise of medicines, medical products and devices of the Ministry of Health and social development of the Republic of Kazakhstan)
- Republic of Belarus State system of control and compliance monitoring of medicines circulation (***Dolgolikova A.N.*** — Deputy Head of the Pharmaceutical Inspection and organization of drug supply to the Ministry of Health of the Republic of Belarus)
- Regulation of medical products circulation in Argentina. (***Dr. Chiale K.*** — National Administration of Drugs, Foods and Medical Devices of Argentina — ANMAT)
- Republic of Serbia State system of pharmaceuticals quality control. Challenges and solutions (***Malesevic M.*** — Medicines and Medical Devices Agency of Serbia).

– People's Republic of China control and compliance monitoring of medicines and medical devices circulation at the regional level (***Li Tao*** — Division Director of Drug Registration of the Food and Drug Administration of Shandong Province, ***Liu Dou*** — Deputy Director of the drug manufacturing compliance monitoring Department, Food and Drug Administration of Shandong Province, ***Feng Shi*** — Shandong Institute for Food and Drug Control)
– Russia's participation in «Pangea», an international police operation to prevent the sale of fasified and counterfeit medicines on Internet (***Shishova T.V.*** — Deputy Head of the 3rd Division of the National Interpol Bureau of the Ministry of Internal Affairs of Russia)
– Online pharmaceutical black market. Trends and analytics (***Krivulin R.A.*** — Head of Brand Point Protection, the company Group-IB)

Manufacturing of medicines. New development trends.

Co-chairs: ***Tsyb S.A.*** — Deputy Minister of Industry and Trade of the Russian Federation, ***Dmitriev V.A.*** — CEO of the Association of Russian Pharmaceutical Manufacturers.

– Support for small innovative «drug development and commercialization» companies (***Livshits H.V.*** — Director of Skolkovo Fund BMT cluster medical programs)
– MIPT Biopharmaceutical building. New Moscow region R&D opportunities (***Korzinov O.M.*** — Executive Director of the «Severny» Biofarm cluster and MIPT (МФТИ) Center for Living Systems)
– Manufacturing innovative drugs. Case study by «Celltrion, Inc.» (***Lee Hyukjae*** — Vice-President of «Celltrion, Inc.»)
– Innovation in the pharmaceutical sector, new approaches to developing medicines New dosage forms and delivery methods (***Zarubina K.*** — senior analyst of «Skolkovo» BMT Cluster)
– Quality of medicines. Packaging impact on quality (***Hasan Sezer*** — Sales Manager of Aclar, ***Nigrutsa A.*** — Aclar RF/CIS business development Manager)
– The new dosage forms and methods of drug delivery for transdermal systems (***Dr. Kramer J.*** — Executive Director of PHAST GmbH, Germany)

29 October
13.00–16.00
«Gamma-Delta» Building,
«Moscow 1» Hall

Breakout session
with simultaneous English translation

– Domestic manufacturing as a strategy for Russian pharmaceutical industry marketability (***Kopachevskya S.V.*** — director of «Naukoprofi» research and manufacturing division of N.N. Blokhin Russian Cancer Research Center)
– Pharmaceutical market trends (***Shulyak S.A.*** — CEO of DSM GROUP)
– Efficient leadership team as a prerequisite for a pharmaceutical manufacturer success (***Zabazarnykh Y.S.*** — «CONTACT AGENCY» InterSearch Group)

29 October
13.00–18.00,
«Gamma-Delta» Building,
«Moscow 2» Hall

Breakout session

Ensuring availability of pharmaceutical care

Co-chairs: ***Parhomenko D.V.*** — Deputy Head of Roszdravnadzor, ***Maksimkina E.A.*** — Director of the Department of medicines provision and regulation of medical devices circulation of the Ministry of Health of Russia,

Developing medical products lists within the framework of the state guarantees program

– Adding medicines and treatment methods to state guarantees and costs coverage program (***Maksimkina E.A.*** — Director of the Department of medicines supply and medical devices regulation of the Russian Ministry of Health)
– Using results of the clinical-economic evaluations in development of restrictive lists of medical products (***Kulikov A.Y.*** — Professor, First Moscow State Medical University)
– Implementation of the state guarantees program: correlation between the medicines lists and health care standards (***Komissinskaya I.G.*** — Pharmaceutical Department Chair, Kursk State Medical University)
– Quality of pharmaceutical care. Role of GSL (General Sales List) (***Ignatieva N.V.*** — Executive Director of the Russian Association of Pharmacy Chains)

Pricing: current issues and solutions

– Pricing of vital and essential medicines (***Antipov D.V.*** — Deputy Director of the Department of the development of SME and competition of the Russian Ministry of Economic Development)
– State regulation of medicine prices (***Starih D.A.*** — Head of the Department of price registration for vital and essential medicines, Department for State Regulation of The Circulation of Medicines, Russian Ministry of Health)

– Calculation methodology and price registration for vital and essential medicines under 100 rubles (***Daragan N.K.*** — Chairman of the Coordination Council of the Association of pharmaceutical products Manufacturers)
– Impact assessment for various pricing policies on the availability, budget, innovations and other facets of medicines provision (***Yagudina R.I.*** — Professor, Moscow)

Medicines and medical products circulation in the Customs Union and the Eurasian Economic Community. New ways of effective cooperation

29 October
13.00–15.00
«Gamma-Delta» Building,
«Rostov» Hall

Breakout session

Co-chairs: ***Trapkova A.A.*** — deputy Head of the Division of State Medical Products Quality Control, Roszdravnadzor, ***Boytsov V.B.*** — Director of Technical Regulation and Accreditation Department of the Eurasian Economic Commission, ***Pak L.Y.*** — Department Head, Almaty medical and pharmaceutical activity Control Committee

– Eurasian Economic Union Treaty and Eurasian Economic Union International treaties on medicines and medical devices circulation. (***Shchekin D.A.*** — Head of the Harmonization of Technical Regulation in Industries Section, Department of Technical Regulation and accreditation of Eurasian Economic Commission
– Developing common approach to drug market regulation within the Eurasian Economic Union. (***Rozhdestvensky D.A.*** — Deputy Head of the Harmonization of Technical Regulation in Industries Section, Department of Technical Regulation and accreditation of Eurasian Economic Commission)
– Requirements for EURASIAN ECONOMIC UNION member states pharmaceutical inspectorates (***Timoshina V.V.*** — Leading scientist on medicines quality of the Ministry of Health of the Republic of Belarus)
– Republic of Kazakhstan Pharmaceutical industry development prospects in the framework of the Eurasian Economic Union (***Pak L.Y.*** — Department Head, Almaty medical and pharmaceutical activity Control Committee)
– Regulation of medicines import and export in Eurasian Economic Union (***Trapkova A.A.*** — Deputy Head of the Department of organization of state quality control of medical products of Roszdravnadzor)

29 October
16.15–18.30
«Gamma-Delta» Building,
«Moscow 1» Hall

Breakout session
with simultaneous English translation

The role of the logistics system in ensuring the quality and accessibility of medicines and medical devices

Chair: ***Trapkova A.A.*** — deputy Head of the Division of State Medical Products Quality Control, Roszdravnadzor

- Mass serialization (***Lery F.-X.*** — Head of Pharmaceutical Care Section, Consumer Health Protection and Anti-Counterfeiting — EDQM)
- The system of medicines traffic serialization and control in supply chain of Turkey (***Dr. Kerman*** — Agency for Medicines and Medical Devices Turkey)
- Full implementation of the serialization project in pharmaceutical industry (***Dr. M. Aman*** — Project Manager, International Logistics Department of F. Hoffmann-La Roche, Switzerland)
- Role of API and FPP manufacturers in ensuring medicines safety on the territory of the Eurasian Union (***Kardash E.A.*** — CEO of «Polysan» Scientific Technological Pharmaceutical Company)
- Quality of medicines and «Cold Chain» (***Viazmina T.M.*** — deputy director of Pharmstandard JSC)
- The concept of logistic support for physical distribution of pharmaceutical products, as a factor to increase efficiency of the preferential drug coverage system in Samara Region in 2012-2014 (***Litvishkov A.E.*** — deputy director on economics, finances, marketing and logistics, head of the department of preferential drug coverage, «Pharm SKD»)
- Quality management for physical distribution of pharmaceutical products (***Chukreeva N.V.*** — Director of pharmaceutical practices of JSC «Servier»)

30 October

Expert evaluation and registration of medications. Challenges and Solutions.

Co-Chairs: ***Tsyndymeev A.G.*** — Director of Department of State regulation of circulation of drugs, Russian Ministry of Health, ***Mironov A.N.*** — General Director, «Scientific Centre for expert evaluation of Medical Products», Russian Ministry of Health

- Development of the State Regulation of the Circulation of Pharmaceuticals (***Tsyndymeev. A.G.*** — Director of Department of State regulation of circulation of drugs, Russian Ministry of Health)
- Current State and Priority Areas of Development ***(Mironov A.N.*** — General Director, «Scientific Centre for expert evaluation of Medical Products», Russian Ministry of Health)
- Prospective R&D trends for improving medications expert evaluation (***Merkulov V.A.*** — First Deputy General Director, «Scientific Center for expert evaluation of Medical Products», Russian Ministry of Health)
- General principles of organization of expert evaluation at the «Scientific Center for expert evaluation of Medical Products» (***Sakaeva I.V.*** — Deputy Director General for expert evaluation of pharmaceuticals, «Scientific Center for expert evaluation of Medical Products», Russian Ministry of Health)
- Results of the «Scientific Center for expert evaluation of Medical Products» research activity as a basis for evaluation of quality, efficacy and safety of medications (***Bunyatyan N.D.*** — Deputy General Director for Research and Development, «Scientific Center for expert evaluation of Medical Products», Russian Ministry of Health)
- Planning and running pre-clinical and clinical research and writing label claim for pack insert text. Practice of expert evaluation. (***Vasiliev A.N.*** — Director, Center for FPP expert evaluation and inspection, «Scientific Center for expert evaluation of Medical Products», Russian Ministry of Health)
- Special features of expert evaluation of biopharmaceuticals: Data comparability when making changes in manufacturing (***Bondarev V.P.*** — Director, The Centre for Expert Evaluation and Control of Medical Immuno-biological Preparations, «Scientific Center for expert evaluation of Medical Products», Russian Ministry of Health)
- Current issues of medications quality evaluation at the registration and product modification stages (***Kovaleva E.L.*** — Deputy Director Center for FPP expert evaluation and inspection, «Scientific Center for expert evaluation of Medical Products», Russian Ministry of Health)

30 October
09.00–15.00
MCH «Izmailovo»

Breakout session

– Immuno-biological drugs quality evaluation as a part of Russian Ministry of Health requests and mandatory certification. (***Movsesyants A.A.*** — Head of Testing Center for Medical Immuno-biological Preparations Quality Assessment, «Scientific Center for expert evaluation of Medical Products», Russian Ministry of Health)
– Abnormal toxicity: historical development and contemporary approach (***Dr. S. Osborne*** — team leader, regulatory relations in Russia, the European Federation of Pharmaceutical Industries and Associations)
– Educational Programs of the «Scientific Center for expert evaluation of Medical Products», Russian Ministry of Health (***Yagudina R.I.*** — Director of Center for Educational Programs, «Scientific Center for expert evaluation of Medical Products», Russian Ministry of Health)
– Drug safety data evaluation (***Romanov B.K.*** — Director, Center for expert evaluation of drug safety, «Scientific Center for expert evaluation of Medical Products», Russian Ministry of Health)
– WHO good pharmacopoeia practices (GPhP) in the development of Pharmacopoeia articles for the Russian State Pharmacopoeia. (***Sakanyan E.I.*** — Director of the Pharmacopeia and International cooperation center, Scientific Center of Assessment of Medical Products, Russian Ministry of Health)

30 October
09.00–12.00
«Gamma-Delta» Building,
«Moscow 1» Hall

Breakout session

Good manufacturing practices: steps toward success

Co-chairs: ***Kolotilova O.N.*** — Director, Pharmaceutical and Medical Industry Development Department, Russian Federation Ministry of Industry and Trade, ***Dmitriev V.A.*** — CEO, Association of Russian Pharmaceutical Manufacturers

– Implementation of Good Manufacturing Practice standards and quality control for medicinal products byRussian enterprises. First year review. (***Kolotilova O.N.*** — Director, Pharmaceutical and Medical Industry Development Department, Russian Federation Ministry of Industry and Trade)
– Pitfalls in implementing Good Manufacturing Practice standards and quality control for medicinal products. Russian company case study (***Pshenichnikov V.G.*** — Executive Director of «Synthesis»)
– QP (Qualified Person) in pharmaceutical manufacturing (***Maksimkina E.A.*** — Director of the Division for medicine provision and medical products regulation, Russian Ministry of Health
– QP (Qualified Person) in pharmaceutical manufacturing — current challenges (***Beregovych V.V.*** — Department Chair, Industrial Pharmacy, First Moscow State Medical University)
– QP (Qualified Person) in pharmaceutical manufacturing: international practices (***Chazanchuk M.V.*** — Manager, Regulatory Affairs, LLC «Novo Nordisk»)

– QP (Qualified Person) in European pharmaceutical manufacturing. Functions, rights and duties (National Agency for safety of medicines and medical devices, France)
– Quality System — key element in pharmaceutical industry development (***Alesh Rotar*** — Krka Board Member and R&D director, Krka)
– GMP is a law. What's next? (***Dmitriev V.A.*** — CEO, Association of Russian Pharmaceutical Manufacturers)

Licensing of pharmaceutical activity as a key quality performance indicator

30 October
9.00–12.00
«Gamma-Delta» Building,
«Moscow 2» Hall

Breakout session

Chair: ***Krupnova I.V.*** — Head of the Department of licensing and enforcement of mandatory requirements of Roszdravnadzor

– Legal regulation for circulation of narcotic drugs, psychotropic substances and their precursors, harmonization of the Russian Federation regulatory acts with generally recognized principles and norms of international law in combating narcotic drugs and precursors circulation (***Nikolaeva, N.M.*** — Head of Department of the legal regulations for pharmaceutical activities, narcotic drugs and psychotropic substances circulation, Department of medicines supply and regulation of medical devices circulation , Russian Ministry of Health)
– Current legal regulations of pharmaceutical activity. Outlook and current issues (***Ladygina I.P.*** — Consultant of the Department of the legal regulations for the pharmaceutical activities, narcotic drugs and psychotropic substances, Department of medicines supply and regulation of medical devices circulation, Russian Ministry of Health)
– Licensing: concerns and solutions at the current stage of pharmaceutical business development (***Maydykova E.E.*** — Head of the Department of licensing and healthcare quality control, Moscow region Ministry of Health)
– Protection of legal entities and individual entrepreneurs' rights in implementation of the state control of medicines circulation (***Krupnova I.V.*** — Head of the Department of licensing and enforcement of mandatory requirements of Roszdravnadzor)

– Sale of «strong drugs» in pharmacies under the new legislation, current challenges and solutions (***Nevolina E.V.*** — Director of the Non-commercial partnership for the development of the pharmacy industry «Pharmacy Guild»)
– Pharmaceutical staff: international standards and Russian outlook (***Egorova S.N.*** — Department Chair, Department of Pharmacy, Kazan Medical University)

30 October
09.00–12.00
«Gamma-Delta» Building,
«Rostov» Hall

Breakout session

Registration of medical devices: legal regulation and current issues

Co-chairs: ***Borzik I.K.*** — Deputy Head ofRoszdravnadzor, ***Antonov V.S.*** — Deputy Director General FGBI «Centre for Monitoring and clinico-economic expert evaluation» Roszdravnadzor, ***Monogarova I.I.*** — Head of the regulatory treatment of medical devices to ensure the Department of Drug Treatment and management of medical devices Russian Ministry of Health

– Changes in the legal and regulatory environment with regard to the registration of medical devices (***Astapenko E.M.*** — Head of the department of state control and registration of medical devices, Roszdravnadzor)
– Changing medical device registration documents: operating procedures (***Sukhanova M.M.*** — Deputy Head of the department of state control and registration of medical devices, Roszdravnadzor)
– State registration and post-registration monitoring as elements of state control of medical devices circulation in the Republic of Belarus (***Alekseeva A.P.*** — divisional manager, medical devices quality monitoring, Center for Expert Evaluations and Testing in Health, Republic of Belarus)
– The state registration of medical products in the Republic of Kazakhstan (***Mukhamedzhanova G.E.*** — Deputy Director General, National Center of Expert evaluation of Medicines, Medical Devices and medical equipment, Ministry of Health and Social Development of the Republic of Kazakhstan)
– Decision to request necessary materials and information, or to refuse medical device registration (***Ivanov I.V.*** — CEO «Center for Monitoring and Clinical and Economic Evaluation» Roszdravnadzor)
– Medical devices components and accessories: formation procedure (***Nikiforova L.Y.*** — Head of expert evaluation, All-Russian Research and Testing Institute of Medical Engineering, Roszdravnadzor)
– Obtaining expert assessment on ethical validation of tests involving human subjects (*Èsterov I.D* — Russian Federation Ministry of Health)

Proper conduct of clinical studies. What is good and what is bad?

Chair: ***Rogov E.S.*** — Department Head, clinical trials monitoring, Division of organization of medical productsstate quality control, Roszdravnadzor

- Clinical research State control in the Russian Federation (***Rogov E.S.*** — Department Head, clinical trials monitoring, Division of organization of medical products state quality control, Roszdravnadzor)
- Current trends in drug clinical trials (***Melihov O.G.*** — Director, Clinical Research Institute)
- Three myths about clinical trials in Russia (***Stefanov I.V.*** — General Director «Synergy Research Group», ***Afonchikov Y.V.*** — Deputy General Director, «Synergy Research Group»)
- Conducting international multicenter clinical trials: global company case study (***Kosmacheva V.P.*** — Head of Clinical Research, «GSK»)
- Quality control of clinical trials research center (***Putilovsky M.A.*** — Materia Medica Holding)
- Managing research center: researcher's standpoint (***Gordeev I.G.*** — Department chair of Hospital Therapy, department of general medicine, Pirogov Russian National Research Medical University)
- Conducting early phases clinical trials: special features and variations from advanced phases trials (***Grubman M.A.*** — Director, «Atlant CLINICAL»)
- Innovative management of scientific and clinical research and trials (***Popeko N.A., Perechvatov V.V.*** — «Mitoengineering R&D institute, MSU»)
- Good and bad ethical review (***Malikov A.Y.*** — head of the department of pre-clinical and clinical trials of drugs and medical equipment First St. Petersburg State Medical University)
- From pivotal clinical study to 'real-life clinical practice» (lessons learned from observational studies) (***Talibov O.B.*** — Director of Scientific Affairs, Ligand Research, Inc.)
- Provisions for early scientific advice in clinical trials planning (***Kulikov A.Y.*** — Professor, First Moscow State Medical University)

30 October
9.00–15.30
«Gamma-Delta» Building, «Vladimir» Hall

Breakout session

30 October
13.00–16.00
«Gamma-Delta» Building,
«Moscow 1» Hall

Breakout session
with simultaneous English translation

Current issues of drug safety monitoring: «sore spots» and what could be done?

Chair: ***Glagolev S.V.*** — Bureau Deputy Head, Department Head, monitoring of the effectivenessand safetyof medical products, Roszdravnadzor

- Russian Federation legislation changes in regard to drug safety monitoring. Amendments to the Federal Law «On Circulation of Medicines» (***Glagolev S.V.*** — Bureau Deputy Head, Department Head, monitoring of the effectiveness and safety of medical products, Roszdravnadzor)
- Effective use of diverse structured and unstructured data sources on drug safety and underlying technology (***Kaydos K.*** — Vice President of Product Strategy Oracle)
- Best practices and new trends in the identification and management of signals in drug safety (***R. Weber*** — Senior Manager, Product Strategy Oracle)
- Latest pharmacovigilance regulations in the Customs Union (***Efremova I.N.*** — Head of the Republic of Belarus clinical pharmacological laboratory, ***Setkina S.B.*** — Leading scientist of the Republic of Belarus clinical pharmacological laboratory, «Center for Expert evaluation and Testing in Health Care» of the Republic of Belarus)
- Changes in pharmacovigilance procedures in pharmaceutical companies related to the general drug market (***Ermishina O.*** — Member of the Committee for Clinical Research and Pharmacovigilance, Association of International Pharmaceutical Manufacturers)
- Managing pharmacovigilance in the Republic of Crimea and Sevastopol (***Konyaeva E.I.*** — Department head, Clinical Pharmacology and Pharmacotherapy, Crimean State Medical University)

Pharmacy medicines compounding. Legislation and reality

30 October
13.00–16.00
«Gamma-Delta» Building,
«Moscow 2» Hall

Breakout session

Chair: ***Kosenko V.V.*** — Head of the Division of organization of state quality control of medical products of Roszdravnadzor

- Quality of pharmacy compounded medicines (***Kosenko V.V.*** — Head of the Division of organization of state quality control of medical products of Roszdravnadzor)
- Pharmacy compounded medicines: healthcare necessity and development trends (***Egorova S.N.*** — Pharmaceutical Department Chair, Kazan State Medical University)
- Current aspects of pharmacy compounding in the Republic of Tatarstan. Legislation and reality (***Safiullin R.S.*** — Head of Roszdravnadzor regional office in the Republic of Tatarstan)
- Stavropol Region compounding pharmacies. Yesterday, today and tomorrow (***Michaleva I.P.*** — Deputy Head of Roszdravnadzor regional office in the Stavropol Region)
- Controlling pharmacy compounding in Samara Region pharmacies (***Antimonov A.V.*** — Head of Roszdravnadzor regional office in Samara region)
- Contemporary pharmacy compounding (***Nevolina E.V.*** — Director of the «Pharmacy Guild»)
- Pharmacy compounding in the 21st century: global experience review (***Kondratieva B.B.*** — graduate student, Moscow, Yagudina R.I — Professor, Moscow)

Registration of certain types of medical devices

30 October
13.00–17.00
«Gamma-Delta» Building,
«Suzdal» Hall

Breakout session

Co-Chairs: ***Borzik I.K.*** — Deputy Head ofRoszdravnadzor, ***Monogarova I.I.*** — Head of Department of the legal regulations for medical devicescirculation, Department of medicines supply and regulation of medical devices circulation, Russian Ministry of Health)

- Russian medical devices market: past, present and future (***Lukyanov N.A.*** — CEO of «Bureau KM»)
- Transfer of medical devices manufacturing technologies: formula for success (***Sardeson S.*** –International Regulatory Affairs Manager3M, USA)
- Hitachi, Ltd. undertakings in the medical industry (***Takao Kuboniva*** — a leading expert and head of the division of proton therapy, Hitachi, Ltd., Power Systems Company, Japan)

- Results presentation for on-site technical testing of medical devices (***Nikiforova L.Y.*** — Head of expert evaluation, All-Russian Research and Testing Institute of Medical Engineering, Roszdravnadzor)
- Registering medical device as a medical device with a measuring function (***Esterov I.D.*** — Russian Federation Ministry of Health)
- Special aspects of testing mobile medical complexes (***Rybalov A.A.*** — Director of Laboratory for testing mobile medical complexes, All-Russian Research and Testing Institute of Medical Engineering, Roszdravnadzor)
- Requirements for paperwork to be provided by the applicant based on clinical trial results (***Preobrazhensky A.V.*** — Adviser for Department, of medical devices registration Division of organization of state quality control of medical products of Roszdravnadzor)
- Clinical trials of implantable medical devices (***Kniga V.V.*** — Head of clinical testing and maintenance of medical devices, medical center № 1, Office of the President of the Russian Federation)
- Substantiation of submitted clinical data for implantable dental medical devices (***Prosycheva O.O.*** — Maxillofacial Surgery teaching fellow at Moscow State Dental University, Russian Federation Ministry of Health, of the Clinical Dentistry Center, Russia Federal Medical and Biological Agency)
- Software as a medical product: current requirements (***Mikheyev M.S.*** — Director of Laboratory for testing of medical devices software, All-Russian Research and Testing Institute of Medical Engineering, Roszdravnadzor)

Special aspects of registration of medical devices for in vitro diagnostic

Co-Chairs: ***Antonov V.S.*** — Deputy Director General Center for Monitoring and Clinical and Economic Evaluation, Roszdravnadzor, ***Tarasenko O.A.*** — Deputy Director General, All-Russian Research and Testing Institute of Medical Engineering (VNIIIMT), Roszdravnadzor, ***Ivanov I.V.*** — Director General, «Center for Monitoring and Clinical and Economic Evaluation» Roszdravnadzor

- Scientific-methodological approach to state control of quality, efficiency and safety of medical devices for in vitro diagnostic (***Tarasenko O.A.*** — Deputy Director General, All-Russian Research and Testing Institute of Medical Engineering (VNIIIMT), Roszdravnadzor.)
- Current state of regulations for the circulation of in vitro diagnostics medical devices. International and domestic practices (***Manzenyuk I.N.*** — Deputy Head of the Department of Molecular Diagnostics and Epidemiology, Central Research Institute of Epidemiology, Federal Service for Supervision of Consumer Rights Protection and Human Welfare)
- Special aspects of pre-registration preparation and clinical testing of growth media, multiplex tests, complex analyses (***Sukhina M.A.*** — leading scientist, All-Russian Research and Testing Institute of Medical Engineering (VNIIIMT), Roszdravnadzor)
- Requirements and recommendations for the paperwork for registration of medical devices for in vitro diagnostics (***Leoshkina N.A.*** — expert, Department of quality, efficiency and safety of medical devices, Center for Monitoring and Clinical and Economic Evaluation, Roszdravnadzor)
- National, multinational and international standards on safety and efficacy of medical devices for in vitro diagnostic (***Shubin Y.F.*** — Associate Professor, Department of Clinical Laboratory Diagnostics, Pirogov Medical University, Russian Ministry of Health)
- Clinical laboratory trials of kits for in vitro diagnostic: general requirements and procedures (***Dolgov V.V.*** — Department Chair of Clinical laboratory Diagnostics «Russian Medical Academy of Postgraduate Education», Russian Ministry of Health)
- Statistical evaluation of the results of clinical trials of medical devices for in vitro diagnostic (***Antonov V.S.*** — Deputy Director General, Center for Monitoring and Clinical and Economic Evaluation, Roszdravnadzor)
- International Forum of Regulators of medical devices (IMDRF) recommendations on regulatory authority paperwork required to access market of medical devices for in vitro diagnostic (***Kolosova O.A.*** — Head of registration and certification group, «Roche Diagnostics Rus»)

30 October
13.00–17.00
«Gamma-Delta» Building, «Rostov» Hall

Breakout session

30 October
15.15–18.30
MCH «Izmailovo",

Breakout session
with simultaneous
English translation

Biotech drugs - global trends of global development

Co-chairs: ***Tsyndymeev A.G.*** — Director of Department of State regulation of drugs circulation, Russian Ministry of Health, ***Vasiliev A.N.*** — Director, Center for Expert Evaluation of Medicinal Products

- Developing biotech drugs regulatory system in the Russian Federation (***Tsyndymeev A.G.*** — Director of Department of State regulation of drugs circulation, Russian Ministry of Health)
- Practical aspects of biosimilars assessment for the purpose of registration in the Russian Federation. «Pitfalls» and concerns — as viewed by an expert institution (***Vasiliev A.N.*** — Director, Center for Expert Evaluation of Medicinal Products)
- Global trends in biotech drugs and biosimilars regulation, including interchangeability issues (***Dr. F. Bisordi*** — member of Biotherapeutics Committee, International Federation of Pharmaceutical Manufacturers and Associations)
- Biosimilars development and European market launch (***Dr. U. Jaegle*** — Regulatory Affairs Officer, Sandoz)
- Biopharmaceuticals: Global trends and Russian experience (***Maksumova L.D.*** — Vice-President for Strategic Development, «Geropharm»)
- Clinical aspects of biopharmaceuticals therapeutic replacement (***Alekseeva E.I.*** — Head of the Department of Rheumatology, Research Centre for Children's Health), RAS

The conference programandorder of presentationscould be changed