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APPLIED RESEARCH CONFERENCE ON *MODERN APPROACHES TO MEDICINAL PRODUCT EVALUATION AND AUTHORISATION 'REGLEK-2021'*

November 23-25, 2021
Moscow

DRAFT PROGRAMME OF THE CONFERENCE

November 23
Session 1

Hall 1
09.00-09.30 Opening address

Hall 1
09.30-12.15 Plenary session

- Topic TBA (**Glagolev S.V.** – Deputy Minister of Health of the Russian Federation)
- Upcoming expansion of EAEU abbreviated approval pathways portfolio (**Nurashev T.B.** – Director, Technical Regulation and Accreditation Department, Eurasian Economic Commission (EEC))
- WHO Prequalification of medicines programme: aims and procedures (**Vujnović M.** – Head of the WHO Office in Russia)
- Procedure for accelerated assessment of medicinal products (**Mignot H.** – Regulatory Affairs Manager, Committees and Quality Assurance Department, EMA)
- Unspecified impurities in medicinal products: the case of nitrosamines (**Keitel S.** – Ph.D., Former Director of the EDQM)
- Drug safety on a global scale: the use of a large repository (**Le Louët H.** – CEO, Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, **Rausch C.** – Special Advisor to the CEO, Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring)
- Topic TBA (**Kosenko V.V.** – General Director, FSBI 'SCEEMP', Ministry of Health of Russia)
- Paul Ehrlich Institute in the centre of the fight against the CoV-2 pandemic (**Cichutek K.** – President of the Paul Ehrlich Institute)
- Radioisotope products and the medicine of the future (**Jalilian A.R.** – Radioisotope & Radiopharmaceutical Chemist, Technical Officer, Radioisotope Products and Radiation Technology Section, Department of Nuclear Sciences and Applications, International Atomic Energy Agency)

12.15-13.00 Break

Hall 2
13.00-15.30 Breakout session 1.1.
Registration Dossier Lifecycle Management

Moderators: **Merkulov V.A.** – Deputy General Director for Medicinal Products Evaluation, FSBI 'SCEEMP', Ministry of Health of Russia, **Rozhdestvenskiy D.A.** – Head of the Section for Coordination of Activities in the Sphere of Medicines' and Medical Products' Circulation, Technical Regulation and Accreditation Department, EEC

- Approaches to combining changes in registration dossiers (**Rozhdestvenskiy D.A.** – Head of the Section for Coordination of Activities in the Sphere of Medicines' and Medical Products' Circulation, Technical Regulation and Accreditation Department, EEC)
- Designing procedures to introduce changes to registration dossiers (**Zhuravleva O.B.** – Deputy Director of the Centre for Examinations and Tests in Health Service, RUE, Ministry of Health of the Republic of Belarus)
- Use of supportive data for registration dossier maintenance (PSUR, RWD, Literature Reviews) (**Efremova I.N.** – Supervisor of the Republican Clinical and Pharmacological Laboratory, Centre for Examinations and Tests in Health Service, RUE, Ministry of Health of the Republic of Belarus)
- Focus on RWE use throughout a medicinal product lifecycle: the Danish experience (**Poulsen P.** – Senior Market Access Manager, Denmark, Pfizer)
- Elaboration of mixed dossiers to support authorisation of medicinal products historically present in the national market (**Rozhdestvenskiy D.A.** – Head of the Section for Coordination of Activities in the Sphere of Medicines' and Medical

Products' Circulation, Technical Regulation and Accreditation Department, EEC)
- Discussion

Hall 3
13.00-15.30 Breakout session 1.2.
R&D Integration into Authorisation Procedures

- Interconnection between PQS and R&D (**Makarenko I.E.** – Head of the Medical Department, GEROPHARM, OOO)
- Use of R&D transfer results in registration dossiers
- R&D results evaluation during Module 2 review
- R&D (manufacturing) in registration dossiers: interdisciplinary interaction of a regulatory specialist and a medicinal product manufacturer (**Chukreyeva N.V.** – Director for Pharmaceutical Activities in Russia and the EAEU, Servier, AO)
- Case studies

Hall 1
13.00-15.30 Breakout session 1.3.
Development of International Compendial Requirements and the EAEU Pharmacopoeia: from Idea to Implementation (Part 1)

Moderators: **Kosenko V.V.** – General Director, FSBI 'SCEEMP' of the Ministry of Health of Russia, **Tulegenova A.U.** – Chairperson, EAEU Pharmacopeial Committee, Head of the Centre for Modernisation of the State Pharmacopoeia of the Republic of Kazakhstan

- Pharmacopoeial standardisation in the EAEU: current standing and future perspectives (**Shchekin D.A.** – Head of the Secretariat, EAEU Pharmacopeial Committee, Deputy Head of the Section for Coordination of Activities in the Sphere of Medicines' and Medical Products' Circulation, Technical Regulation and Accreditation Department, EEC)
- EAEU Member States' approaches to elaboration of the Compendial reference standards system (**Tulegenova A.U.** – Chairperson, EAEU Pharmacopeial Committee, Head of the Centre for Modernisation of the State Pharmacopoeia of the Republic of Kazakhstan, a representative of the FSBI 'SCEEMP', Ministry of Health of Russia)
- EAEU Pharmacopeia requirements to dosage forms: considerations for setting specifications and product quality specification files (**Kovaleva E.L.** – Vice-Chairperson of the EAEU Pharmacopeial Committee, Deputy Director of the Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Discussion

15.30-16.00 Break

Hall 2
16.00-18.00 Breakout session 1.4.
Special Considerations for Clinical Studies During the Pandemic

Moderator: TBA

- Special considerations for clinical studies control during the pandemic (**Murzich T.V.** – Head of the Department of Clinical Trials Control, Department of State Quality Control of Medical Products, Federal Service for Surveillance in Healthcare)
- Relevant issues of clinical studies regulation amid the ongoing pandemic (**Gudkov K.V.** – Clinical Research Director, AstraZeneca Russia)
- Electronic medical records (EMRs): international regulatory requirements and potential use of the Unified medical information analysis system (UMIAS) as an EMR for remote monitoring in COVID-19 pandemic conditions (**Dubrovin S.M.** – Director of Clinical Site Operations, Pfizer Innovations LLC)
- Discussion

Hall 1
16.00-18.00 Breakout session 1.5.
Development of International Compendial Requirements and the EAEU Pharmacopoeia: from Idea to Implementation (Part 2)

Moderators: **Kosenko V.V.** – General Director, FSBI 'SCEEMP' of the Ministry of Health of Russia, **Tulegenova A.U.** – Chairperson, EAEU Pharmacopeial Committee, Head of the Centre for Modernisation of the State Pharmacopoeia of the Republic of Kazakhstan

- Quality of medicines: new reality and new challenges (**Dörr P.** – Director of the EDQM)
- Ensuring the supply of quality medicines (**Piervincenzi R.** – Chief Executive Officer, United States Pharmacopoeia (USP))
- The International Pharmacopoeia – Focus, Processes and Collaboration with other Pharmacopoeias (**Schmidt H.** – WHO International Pharmacopoeia)
- EAEU Pharmacopoeia Guidelines for elaboration of monographs on
  - Small molecules (a representative of the National Centre for Expertise of Medicines and Medical Devices, Committee for Quality Control and Safety of Goods and Services, Ministry of Healthcare of the Republic of Kazakhstan)
  - Herbal medicinal products (**Strekha I.S.** – Deputy Supervisor of the Laboratory of Pharmacopoeial and

Pharmaceutical Analysis, Centre for Examinations and Tests in Health Service, RUE, Ministry of Health of the Republic of Belarus)
- Biologicals (a representative of the FSBI 'SCEEMP', Ministry of Health of Russia)
- Radiopharmaceuticals (a representative of the National Centre for Expertise of Medicines and Medical Devices, Committee for Quality Control and Safety of Goods and Services, Ministry of Healthcare of the Republic of Kazakhstan)

– Discussion

Hall 3
16.00-17.30 Breakout session 1.6.
Transitional Challenges: Current Authorisation Procedure in Russia

Moderator: **Simonova A.V.** – Deputy Head of the Management and Control Division, FSBI 'SCEEMP', Ministry of Health of the Russian Federation

Russian experts will continue to adhere to a range of articles of Federal Law No.61-FZ 'On circulation of medicines' up to 2025. Consequently, the number of MoH assignments does not decline and sometimes even grows. How can we avoid multiple requests? What should be considered at the time of dossier submission to provide experts with all the necessary information from the beginning? This session will address case studies and analyse the most common applicant mistakes and flaws in regulatory submissions.

– Discussion

Hall 1
17.30-18.00 Closing remarks of the first day

Speakers and topics are under discussion. The draft is subject to change.

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DRAFT PROGRAMME OF THE CONFERENCE

November 24
Session 2

Hall 1
10.00-13.00 Breakout session 2.1.
A Review of the EAEU Pharmaceutical Legislation (in Force, in the Process of Amendment and under Development)

Moderators: **Trapkova A.A.** – Deputy General Director, FSBI 'SCEEMP' of the Ministry of Health of Russia, **Rozhdestvenskiy D.A.** – Head of the Section for Coordination of Activities in the Sphere of Medicines' and Medical Products' Circulation, Technical Regulation and Accreditation Department, EEC

- New procedures for medicinal products authorisation (the latest changes in the EAEU Marketing authorisation rules) (**Kravchuk A.M.** – Deputy Head of the Section for Coordination of Activities in the Sphere of Medicines' and Medical Products' Circulation, Technical Regulation and Accreditation Department, EEC)
- Pharmacovigilance: upcoming regulatory changes (**Setkina S.B.** – Member of the Working Party for Elaboration of Common Approaches to Medicinal Products Regulation in the EAEU, Head of the Drug Safety Division, BIOCAD, ZAO)
- Review of the EEC regulations adopted in 2020-2021: studies, manufacturing and evaluation of medicinal products (**Rozhdestvenskiy D.A.** – Head of the Section for Coordination of Activities in the Sphere of Medicines' and Medical Products' Circulation, Technical Regulation and Accreditation Department, EEC)
- Pharmaceutical inspection types in the context of medicinal products registration: expert approach (**Trapkova A.A.** – Deputy General Director, FSBI 'SCEEMP', Ministry of Health of Russia)
- Discussion

Hall 2
10.00-13.00 Breakout session 2.2.
Preparation of Dossier Module 3: Requirements to Product Quality Specification Files (Part 1)

Moderators: **Kovaleva E.L.** – Deputy Director of the Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP' of the Ministry of Health of Russia, **Kravchuk A.M.** – Deputy Head of the Section for Coordination of Activities in the Sphere of Medicines' and Medical Products' Circulation, Technical Regulation and Accreditation Department, EEC

- Special considerations for preparation of EAEU quality specification files vs. national quality specification files (**Ponomarenko A.A.** – Deputy Head of the Division 4 on Medicinal Products' Quality, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP' of the Ministry of Health of Russia)
- Control of organic impurities in medicinal products (**Matveeva O.A.** – Head of the Division 3 on Medicinal Products' Quality, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Requirements for herbal medicinal products' specification files (**Frolova L.N.** – Chief Expert, Division 4 on Medicinal Products' Quality, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Animal-derived medicines: selection of quality attributes for specifications, impurity control, and special considerations for dossier Module 3 (**Prokopov I.A.** – Head of the Division 4 on Medicinal Products' Quality, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP' of the Ministry of Health of Russia, **Pryakhina E.A.** – Leading Expert, Division 3 on Medicinal Products' Quality, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Microbiological quality requirements: justification of reduced testing under the EAEU Marketing authorisation procedure (**Gunar O.V.** – Head of the Microbiology Laboratory, Testing Centre for Evaluation of Medicinal Products' Quality, FSBI 'SCEEMP', Ministry of Health of Russia)
- Justification of proposed expiry dates and storage conditions (**Belanova A.I.** – Chief Expert, Division 3 on Medicinal Products' Quality, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Common mistakes in labelling and package design mock-up submissions (**Shestakova A.K.** – Leading Expert, Division 4

on Medicinal Products' Quality, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)

Hall 3
10.00-13.00 Breakout session 2.3.
Accelerated Authorisation of Medicinal Products

Moderator: **Merkulov V.A.** – Deputy General Director for Medicinal Products Evaluation, FSBI 'SCEEMP', Ministry of Health of Russia, a representative of the Ministry of Health of the Russian Federation

- Acceleration of medicinal products authorisation based on incomplete data (**Goryachev D.V.** – Director, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Regulatory arrangements to provide patients with rapid access to up-to-date therapies (**Luchinina I.V.** – Director, Medicines Registration Department, BIOCAD, ZAO)
- Accelerated review and authorisation: international practices (EMA/FDA) and market needs (**Krechetov A.O.** – Director, Regulatory Liaison Department, GENERIUM, AO)
- Regulatory flexibility for orphan drugs: developers' expectations (**Markova O.A.** – Head of the Scientific Department, Clinical Studies and Pharmacovigilance Department, GENERIUM, AO)
- Accelerated authorisation: lessons learned in 2020-2021 (**Samsonov M.Yu.** – Director of the Medical Department, R-Pharm, AO)

13.00-14.00 Break

Hall 1
14.00-16.00 Breakout session 2.4.
Regulatory Procedures According to the EAEU Rules: Current Implementation Challenges and Solutions

Moderator: **Rychikhina E.M.** – Head of the Management and Control Division, FSBI 'SCEEMP' of the Ministry of Health of Russia

According to the EAEU Rules for marketing authorisation and expert assessment of medicinal products for human use any regulatory procedure can be regarded as part of a dossier lifecycle management project. Such projects are never the same: the dates, requirements and objectives vary. Up to the end of 2025, MAHs will be placing the utmost importance on bringing dossiers for their medicinal products in compliance with EAEU requirements, amending dossiers, and gaining approval for new products. These different procedures have more in common than it appears. Each of them can be divided into steps comprising similar processes. During this session, we will discuss the following questions that are important to get stable results:

- How to follow the sequence of regulatory procedures?
- What is the scope of activities?
- How to identify and optimise each of the steps?
- How to define objectives and levels of priority?
- How to evaluate timeframes and risks?

We will also address the applicability of different procedures for a typical dossier lifecycle in order to make regulatory steps of the projects the most efficient.

- Discussion

Hall 2
14.00-16.00 Breakout session 2.5.
Preparation of Dossier Module 3: Requirements to Product Quality Specification Files (Part 2)

Moderators: **Kovaleva E.L.** – Deputy Director of the Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP' of the Ministry of Health of Russia, **Kravchuk A.M.** – Deputy Head of the Section for Coordination of Activities in the Sphere of Medicines' and Medical Products' Circulation, Technical Regulation and Accreditation Department, EEC

- Challenges of product quality specification files and registration dossier Module 3 preparation according to EAEU regulations (**Prokofiev O.A.,** Director, Registration Department, Takeda Pharmaceuticals, OOO)
- Changes to the requirements to product quality specification files preparation: a preview of the draft Regulation **(Kravchuk A.M.,** Deputy Head of the Section for Coordination of Activities in the Sphere of Medicines' and Medical Products' Circulation, Technical Regulation and Accreditation Department, EEC)
- Main flaws in preparation of product quality specification files:
  - Common mistakes in preparation of product quality specification files in Russia (**Struzhkova A.A.** – Leading Expert, Division 3 on Medicinal Products' Quality, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
  - A representative of the National Centre for Expertise of Medicines and Medical Devices, Committee for Quality Control and Safety of Goods and Services, Ministry of Healthcare of the Republic of Kazakhstan
  - Main flaws in preparation of product quality specification files in the Republic of Belarus (a representative of the Centre for Examinations and Tests in Health Service, RUE, Ministry of Health of the Republic of Belarus)
- Discussion

Hall 3
14.00-16.00 Breakout session 2.6.
Clinical Studies in EAEU Regulatory Practice

Moderator: **Goryachev D.V.** – Director, Centre for Evaluation and Control of Medicinal Products, of the FSBI 'SCEEMP' of the Ministry of Health of Russia

- The place and principles of clinical studies in a medicinal product development programme in the EAEU (**Goryachev D.V.** – Director, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Clinical development programmes for modified medicinal products (**Solovyova A.P.** – Chief Expert, Division 2 on Medicinal Products' Safety and Efficacy, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Key points in statistical analysis of pivotal clinical study data in the EAEU (types of subgroup analyses and sensitivity tests, checks of underlying assumptions for primary endpoint and secondary efficiency endpoints, additional *post-hoc* analyses, etc.) (**Basova O.I.** – 1st Professional Category Expert, Division 1 on Medicinal Products' Safety and Efficacy, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Practical aspects of dossier evaluation in the case of negative clinical risk-benefit assessment (**Ivanova O.Yu.** – Deputy Head of the Division 1 on Medicinal Products' Safety and Efficacy, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP' of the Ministry of Health of Russia)
- Discussion

16.00-16.30 Break

Hall 1
16.30-18.00 Breakout session 2.7.
Development of Medicines Standardisation in Russia

Moderators: **Kosenko V.V.** – General Director, FSBI 'SCEEMP' of the Ministry of Health of Russia, **Bagirova V.L.** – Director, Institute of Pharmacopoeia and Standardisation in the Area of Medicinal Products Regulation, FSBI 'SCEEMP' of the Ministry of Health of Russia

- The State Pharmacopoeia of the Russian Federation: development perspectives and new approaches to regulatory activities (**Bagirova V.L.** – Director, Institute of Pharmacopoeia and Standardisation in the Area of Medicinal Products Regulation, FSBI 'SCEEMP', Ministry of Health of Russia)
- Compendial reference standards as a key element of the state approach to medicines quality (**Starchak Yu.A.** – Head of the Department for Reference Standard Certification, Institute of Pharmacopoeia and Standardisation in the Area of Medicinal Products Regulation, FSBI 'SCEEMP', Ministry of Health of Russia)
- Quality standardisation of radiopharmaceuticals from the standpoint of the Pharmacopoeia (**Ruziyev R.D.** – Head of the Laboratory of Radiopharmaceutical Products and In-Vitro Diagnostics Reagent Kits, Testing Centre for Evaluation of Medicinal Products' Quality, FSBI 'SCEEMP', Ministry of Health of Russia)
- Modern requirements to abnormal toxicity (**Neugodova N.P.** – Head of the Pharmacology Laboratory, Testing Centre for Evaluation of Medicinal Products' Quality, FSBI 'SCEEMP', Ministry of Health of Russia)
- Discussion

Hall 2
16.30-18.00 Breakout session 2.8.
Laboratory Testing of Medicinal Products

Moderators: **Lutseva A.I.** – Head of the Testing Centre for Evaluation of Medicinal Products' Quality, FSBI 'SCEEMP' of the Ministry of Health of Russia, **Mamashina E.A.** – Chief Expert, Laboratory for Control and Coordination of Testing, Testing Centre for Evaluation of Medicinal Products' Quality, FSBI 'SCEEMP' of the Ministry of Health of Russia

- Practical arrangements of submitting samples and supporting documents for quality assessment according to the EAEU Procedure (**Turundayeva A.A.** – Leading Expert, Laboratory for Control and Coordination of Testing, Testing Centre for Evaluation of Medicinal Products' Quality, FSBI 'SCEEMP', Ministry of Health of Russia)
- Requirements for reference standards, reagents and materials submitted for quality assessment according to the EAEU Procedure: specific requirements for information submitted in the quality section of a registration dossier (**Vaganova O.A.** – Head of the Laboratory of Biotechnological Products, Testing Centre for Evaluation of Medicinal Products' Quality, FSBI 'SCEEMP', Ministry of Health of Russia)
- Assessment of materials on analytical method validation during laboratory testing of medicinal products (**Kuleshova S.I.** – Head of the Laboratory of Antibiotics Testing Centre for Evaluation of Medicinal Products' Quality, FSBI 'SCEEMP', Ministry of Health of Russia)
- Discussion

Hall 3
18.15-18.30 Closing remarks of the second day

Speakers and topics are under discussion. The draft is subject to change.

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DRAFT PROGRAMME OF THE CONFERENCE

November 25
Session 3

Hall 1
10.30-12.00 Breakout session 3.1.
New Horizons for Bioequivalence Studies Regulation

- Bioequivalence of dosage forms for local action (**Rozhdestvenskiy D.A.** – Head of the Section for Coordination of Activities in the Sphere of Medicines' and Medical Products' Circulation, Technical Regulation and Accreditation Department, EEC)
- Bioequivalence of oral dosage forms with minimal absorption (**Solodovnikov A.G.** – Deputy Director of Operations, Statandocs, OOO)
- Biowaiver procedure: special considerations for final reports preparation (**Uvarova N.E.** – 1st Professional Category Expert, Division No.1 on Medicinal Products' Safety and Efficacy, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Discussion

Hall 2
10.00-12.00 Breakout session 3.2.
Some Aspects of e-Dossiers Preparation According to EAEU Procedures in Reference and Concerned Member States. Regulations, Implementation, Challenges and Solutions

Moderators: **Rychikhina E.M.** – Head of the Management and Control Division, FSBI 'SCEEMP' of the Ministry of Health of Russia, **Lednev O.A.** – Head of the Informatisation Division, FSBI 'SCEEMP' of the Ministry of Health of Russia

- Cross-border cooperation: challenges and solutions (**Dyrda E.Ch.** – Head of the Department of Information, Informatics and Analysis, Centre for Examinations and Tests in Health Service, RUE, Ministry of Health of the Republic of Belarus)
- Special considerations for Module 1 preparation in a reference state and in a concerned one (**Lednev O.A.** – Head of the Informatisation Division, FSBI 'SCEEMP', Ministry of Health of Russia)
- Reference State and Concerned State dossiers (the Same or Different Documents)
- Cross-border cooperation
- Introduction of state-specific changes to a dossier in a Concerned Member State
- Practical recommendations for applicant's activities optimisation based on the chosen strategy of medicinal product registration
- Discussion

Hall 3
10.00-12.00 Breakout session 3.3.
Tips and Tricks of the Pharmacovigilance System

Moderators: **Alyautdin R.N.** – Head of the Division for Evaluation of Medicinal Products' Safety, FSBI 'SCEEMP', Ministry of Health of Russia, **Gorelov K.V.** – Deputy Head of the Department of State Quality Control of Medical Products, Head of the Pharmacovigilance Department, Federal Service for Surveillance in Healthcare

- Risk management system: practical aspects of risk assessment and development of risk mitigation strategies (**Setkina S.B.** – Member of the Working Party for Elaboration of Common Approaches to Medicinal Products Regulation in the EAEU, Head of the Drug Safety Division, BIOCAD, ZAO)
- Quality management system and pharmacovigilance (**Ermishina O.S.** – Pharmacovigilance Country Head, Bayer, AO)

- MedDRA in the context of pharmacovigilance and medicinal product information (**Obernikhina E.I.** – Medical Expert, MedDRA Maintenance and Support Services Organisation (MedDRA MSSO)
- Typical non-conformities of PSMFs in registration dossiers to EAEU regulations (**Velts N.Yu.** – Deputy Head of the Division for Evaluation of Medicinal Products' Safety, FSBI 'SCEEMP' of the Ministry of Health of Russia)
- Recommendations for medicinal products safety and efficacy information monitoring in Russia in the context of PV (**Milchakov K.S.** – Scientific Director, Scientific Medical Association 'Litreview')
- Discussion

12.00-13.00 Break

Hall 1
13.00-15.00 Breakout session 3.4.
Expert Evaluation Matters and Special Requirements for Dossier Module 3 Contents for Certain Groups of Medicinal Products: Herbal, Inhaled, Radiopharmaceutical, and Biological Products

Moderator: **Kovaleva E.L.** – Deputy Director of the Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP' of the Ministry of Health of Russia

– Requirements for preparation of product specification files and Module 3 for radiopharmaceuticals (**Lankina E.V.** – 1st Professional Category Expert, Division 3 on Medicinal Products' Quality, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Requirements for preparation of Module 3 'Quality' for biotechnological products (**Volkova R.A.** – Head of the Laboratory of Molecular Biology and Genetic Test Methods, Testing Centre for Evaluation of MIBP's Quality, FSBI 'SCEEMP', Ministry of Health of Russia)
- Inhaled and nasal medicinal products: special considerations for specifications and requirements for pharmaceutical development materials (**Prokopov I.A.** – Head of the Division 3 on Medicinal Products' Quality, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP' of the Ministry of Health of Russia, **Minayeva E.D.** – Leading Expert, Division 4 on Medicinal Products' Quality, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Preparation of Module 3 materials for herbal medicinal products (**Shelestova V.V.** – Chief Expert, Division 4 on Medicinal Products' Quality, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)

Hall 2
13.00-15.00 Breakout session 3.5.
Issues of Risk-Benefit Assessment in the EAEU

Moderator: **Goryachev D.V.** – Director, Centre for Evaluation and Control of Medicinal Products, of the FSBI 'SCEEMP' of the Ministry of Health of Russia

- Pivotal preclinical pharmacology studies of medicinal products (**Engalycheva G.N.,** Chief Expert Division 2 on Medicinal Products' Safety and Efficacy, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Requirements for completing herbal medicinal products' dossiers (**Mikheyeva N.S.** – Chief Expert, Division 1 on Medicinal Products' Safety and Efficacy, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Requirements for package inserts preparation (**Parfenova E.Yu.** – Head of the Department for Dossier Data Unification, Division 1 on Medicinal Products' Safety and Efficacy, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Lessons learned from expert evaluation according to EAEU procedures (**Gubenko A.I.** – Deputy Director of the Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP', Ministry of Health of Russia)
- Discussion

15.00-15.30 Break

Hall 1
15.30-16.30 Round table
Topical Matters of Expert Evaluation of Medicinal Products

Kosenko V.V. – General Director, FSBI 'SCEEMP' of the Ministry of Health of Russia
Trapkova A.A. – Deputy General Director, FSBI 'SCEEMP' of the Ministry of Health of Russia
Merkulov V.A. – Deputy General Director for Medicinal Products Evaluation, FSBI 'SCEEMP' of the Ministry of Health of Russia
Bagirova V.L. – Director, Institute of Pharmacopoeia and Standardisation in the Area of Medicinal Products Regulation, FSBI 'SCEEMP' of the Ministry of Health of Russia
Goryachev D.V. – Director, Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP' of the Ministry of Health of Russia
Kovaleva E.L. – Deputy Director of the Centre for Evaluation and Control of Medicinal Products, FSBI 'SCEEMP' of the Ministry of Health of Russia

Lutseva A.I. – Head of the Testing Centre for Evaluation of Medicinal Products' Quality, FSBI 'SCEEMP' of the Ministry of Health of Russia
Rychikhina E.M. – Head of the Management and Control Division, FSBI 'SCEEMP' of the Ministry of Health of Russia

Hall 1
16.30-17.00 Closing remarks of the third day

Speakers and topics are under discussion. The draft is subject to change.

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