MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

50 years GXP SID& GP

GMP VIII ALL-RUSSIA GMP CONFERENCE

PROGRAM of the VIII All-Russia GMP Conference with International Participation

GMP: Good Quality in the current context

September 27-29, 2023

Ekaterinburg

Ekaterinburg-Expo

SEPTEMBER 27, 2023

9:00–10:00 **Registration of the participants, welcome coffee**

10:00–12:00
Main hall

Plenary session
Best Approaches to Regulation of Medicines in a Multipolar World
Part 1

Questions and topics for discussion:

— Capability of the Russian regulatory system to respond quickly to challenges while sustaining the high quality of medicines
— Global experience of pharmaceutical industry development
— Reducing the dependence on imports and building up the country's own export potential
— Interaction of regulatory authorities in the current environment. Platforms for international cooperation
— International professional industry associations as a tool for advancing GMP guidelines. Global Association of Pharmaceutical Inspectorates
— Models of national regulatory authorities. Modes of interaction in case of the distribution of functions among regulatory authorities. Russia's and different countries' experience
— Mutual recognition. International experience

Moderators:

- **Yelena Denisova,** Deputy Director of Department of Pharmaceutical and Medical Industry Development of the Russian Ministry of Industry and Trade
- **Vladislav Shestakov,** Director of the State Institute of Drugs and Good Practices

Speakers:

- **An official** of the Government of Sverdlovsk region
- **Yekaterina Priezzheva,** Deputy Minister of Industry and Trade of the Russian Federation
- **Sergei Glagolev (online),** Deputy Minister of Health of the Russian Federation
- Rustem Muratov, General Director and the board member of Binnopharm Group
- **Martha Veronica Reyes Alvarez,** Minister of Health of the Republic of Nicaragua
- **Melita Vujnovic,** Representative of the World Health Organization in the Russian Federation
- **Stojanka Ivetic,** pharmaceutical inspector, pharmaceutical inspector, MPh, Sector of Inspection Affairs, Ministry of Health of the Republic of Serbia
- **Rana Musa Ali Al Ali,** Drug Directorate Director, Jordan Food and Drug Administration
- **Belinna binti Abu Bakar (online),** Senior Principal Assistant Director, GMP Section, State Pharmaceutical Regulatory Agency of Malaysia

12:00–12:30 **Coffee break and business communication**

SEPTEMBER 27, 2023

12:30–14:00
Main hall

Session partner:
Binnopharm Group

Plenary session
Best Approaches to Regulation of Medicines in a Multipolar World
Part 2

Questions and topics for discussion:

— EAEU's Strategy-2025: What is it and what for? Results of the first years of the operation of the common pharmaceutical market and medicine registration procedure according to the EAEU guidelines
— Provisional procedure established for 2020–2023 by the national legislation of the EAEU member states for the circulation of medicines in terms of registration of medicines
— Inspections of pharmaceutical manufacturers as per the EAEU guidelines. Establishing uniform approaches
— Challenges Russian pharmaceutical enterprises face while entering the global markets
— Mutual recognition. International experience

Moderators:

- **Alena Launik,** Head of the Department of Pharmaceutical Inspection of the Main Department for Control of Medical Activities and Circulation of Medicines of the Ministry of Health of the Republic of Belarus
- **Vladislav Shestakov,** Director of the State Institute of Drugs and Good Practices

Speakers:

- **Dmitry Rozhdestvensky,** Head of the Division of Coordination of Activities in the field of Regulation of Medicines, Department of Technical Regulation and Accreditation, Eurasian Economic Commission
- **Olga Zhuravleva,** Deputy Director of the Unitary Enterprise "Center for Examinations and Tests in Health Service" of the Ministry of Health of the Republic of Belarus
- **Anar Amirova,** Expert of the 1st category of the Pharmaceutical Examination Department of the Directorate of Drug Examination, National Center for the Examination of Medicines and Medical Devices of the Medical and Pharmaceutical Control Committee of the Ministry of Health of the Republic of Kazakhstan
- **Mirbek Nyshanbaev,** Head of the Registration Division, Department of Drug Supply of the Ministry of Health of the Kyrgyz Republic
- **Madina Sottaeva,** Head of the Pharmaceutical Manufacturing Inspection Department, FSI “State Institute of Drugs and Good Practices” of the Ministry of Industry and Trade of the Russian Federation
- **Theingi Zin,** Senior GMP Inspector, Food and Drug Administration, Myanmar
- Slađana Marsenić, GMP/GDP Inspector, Institute of Medicines and Medical Devices, Montenegro
- **Slađana Marsenić,** GMP/GDP Inspector, Institute of Medicines and Medical Devices, Montenegro
- **Alexander Petrov,** Chair of the Board of Directors of LLC "Plant Medsintez"

SEPTEMBER 27, 2023

14:00–15:00 **Lunch break**

15:00–16:30
Main hall

Panel discussion
Systemic View of Industry Education as a Factor in Outstripping Growth of the Pharmaceutical Industry

Topics for discussion:

— Common approaches to the modernization of industry education to ensure accelerated innovative development of the pharmaceutical industry
— Matching the competencies of specialists with the interests and needs of pharmaceutical enterprises
— Interaction of regulatory authorities on issues of industry education
— International experience in the pharmaceutical industry and expert opinions on the possibilities of applying advanced educational solutions in Russia and in the EAEU space

Moderator:

- **Irina Spichak,** Executive Director of the Eurasian Academy of Good Practices. Doctor of Pharmaceutical Sciences, Professor

Speakers:

- **Yekaterina Priezzheva,** Deputy Minister of Industry and Trade of the Russian Federation
- **Vladislav Shestakov,** Director of the State Institute of Drugs and Good Practices of the Ministry of Industry and Trade of the Russian Federation
- **Lilia Titova,** Executive Director, Union of Professional Pharmaceutical Organizations
- **Irina Novikova,** Director General, GxP News
- **Natalia Pyatigorskaya,** Head of the Department of Industrial Pharmacy, Sechenov University, Corresponding Member of RAS, Doctor of Pharmaceutical Sciences, Professor
- **Rustem Muratov,** General Director and the board member of Binnopharm Group
- **Tatiana Vyazmina,** Quality Director, R-Pharm Group
- **Aziz Dusmatov,** Director of the State Unitary Enterprise “Centre for Good Practices” of the Agency for the Development of the Pharmaceutical Industry under the Ministry of Health of the Republic of Uzbekistan

SEPTEMBER 27, 2023

16:30-17:00 — **Coffee break and business communication**

17:00-18:30
Main hall

Session partner:
Pharmeco Group

Panel session
Inter-Agency Cooperation for Enhancing the Pharmaceutical Market

Questions and topics for discussion:

— Issues of inter-agency cooperation
— Initiation of pharmaceutical inspections as part of registration procedures
— Specifics of releasing medicinal products

Moderator:

- **Dmitry Somov,** Director General a.i. of the Federal State Budgetary Institution "IMTSEUAOSMP" of the Federal Service for Supervision of Healthcare (Roszdravnadzor)

Speakers:

- **Yelena Denisova,** Deputy Director of the Department of the Pharmaceutical and Medical Industry Development of the Ministry of Industry and Trade of Russia
- **An official** of the Ministry of Health of the Russian Federation
- **Anna Babushkina,** Deputy Head of the State Veterinary Supervision Department, Federal Service for Veterinary and Phytosanitary Supervision
- **Olga Zhuravleva,** Deputy Director of the Unitary Enterprise "Center for Examinations and Tests in Health Service" of the Ministry of Health of the Republic of Belarus
- **Rakhima Madraimova,** Head of the Pharmaceutical Licensing Department, State Institution "Center for the Safety of Pharmaceutical Products" of the Ministry of Health of the Republic of Uzbekistan
- **Lilia Titova,** Executive Director of the Union of Professional Pharmaceutical Organizations
- **Dr. Boutarene El Haldia Nabiha (online),** Director of Technical Monitoring, Inspection and Pharmacovigilance, Agency for Pharmaceutical Products of Algeria

19:30 – 22:00 — **Evening buffet and networking**

SEPTEMBER 28, 2023

9:00-10:00 **Registration of participants, welcome coffee**

10:00-11:30
Main hall

Panel session
Science-Based Approach to Pharmaceutical Manufacturing

Questions and topics for discussion:

— Goals, objectives and intermediate results of the activities by the Expert Council of the Eurasian Academy of Good Practices
— Approaches to microbiological monitoring of the production environment during the production of medicines. Requirements and application practice.
— Scientific evidence of the toxicological assessment to confirm the possibility of manufacturing medicinal products on the same production line
— Draft Annex 1 – Requirements for Manufacture of Sterile Medicinal Products
— Qualified persons
— Requirements for the manufacture of ATMPs

Moderators:

- **Madina Sottaeva,** Head of Pharmaceutical Manufacturing Inspection Department of the FSI "SID & GP" under the Ministry of Industry and Trade of the Russian Federation

Speakers:

- **Nadezhda Arkhipova,** Deputy Head of the Department for Pharmaceutical Manufacturing Inspection, FSI “SID & GP”, Ministry of Industry and Trade of Russia
- **Natalia Burlakina,** Deputy Head of the Expertise Division of the FSI “SID & GP”, Ministry of Industry and Trade of Russia
- **Asya Chernyavskaya,** Head of the testing center for quality control of medicines LLC IC "ML -STANDARD"
- **Tatiana Vyazmina,** Quality Director, R-Pharm Group
- **Lyudmila Guzevatykh,** Head of the GMP Processes Toxicology Group, R-Pharm Group
- **Olga Maklakova,** Quality Director, Akrikhin Company
- **Ye Xiao (online), GMP inspector,** Food and Drug Inspection Center (CFDI), China

11:30-12:00 **Coffee break and business communication**

SEPTEMBER 28, 2023

12:00–14:00
Main hall

Session partner:
WERTEKS

Panel session
Approaches to Licensing the Manufacture of Medicines

Questions and topics for discussion:

— Current requirements for licensing licensing of pharmaceutical manufacturing and periodic confirmation of compliance as an integral part thereof
— Licensing and GMP certification of quality control laboratories and other outsourced organizations performing separate stages. Approaches in different regions of the world
— Regulatory approaches to ensure compliance with licensing requirements by manufacturers of medicines (preventive measures and unscheduled control (supervisory) measures)
— WHO pre-qualification experience
— International experience in licensing of pharmaceutical manufacturing

Moderators:

- **Yelena Denisova,** Deputy Director of the Department for the Development of the Pharmaceutical and Medical Industry of the Ministry of Industry and Trade of Russia

Speakers:

- **Gelena Grosheva*,** Head of the Department for Licensing and Inspection of the Production of Medicines of the Ministry of Industry and Trade of Russia
- **Dmitry Somov,** Acting Director General of the Federal State Budgetary Institution "IMTSEUAOSMP" of Roszdravnadzor
- **Tatiana Zagumennikova*,** FSI "SID & GP" of the Ministry of Industry and Trade of Russia
- **Alexander Stepanov,** Deputy General Director of Generium JSC
- **Adel Sattarova (online),** Head of the Project Department, the SPbSRIVS of the FMBA of Russia
- **Major General Mohammed Yusuf (online),** Director General of Directorate General of Drug Administration, Bangladesh

14:00 – 15:00 **Lunch break**

15:00–16:30
Main hall

Parallel Event

Panel session
Specifics of Ensuring Compliance with the GMP Guidelines in the Production of Certain Types of Medicines Russian and International Practice

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Questions and topics for discussion:

— Innovations and state-of-the-art technologies in the pharmaceutical industry in the production of sterile medicines.
— Single-Use Systems: Risks. Focused on while inspecting
— Specifics of ensuring the safety of high-tech medicines (ATMPs). What the developer needs to consider
— Control systems of biological products
— Practical challenges of implementing risk analysis of elemental impurities
— Extractables and Leachables: Requirements and Approaches
— Shared manufacturing facilities for solid dosage forms. Experience in implementing a risk-based approach

Moderator:

- **Nadezhda Arkhipova,** Deputy Head of the Pharmaceutical Manufacturing Inspection Department, FSI "SID & GP", Ministry of Industry and Trade of Russia

Speakers:

- **Alexandra Taube (online),** Lead Researcher, Institute for Research and Development, Federal State Budgetary Institution 'SCEEMP' of the Ministry of Health of Russia
- **Nadezhda Arkhipova,** Deputy Head of the Pharmaceutical Manufacturing Inspection Department, FSI "SID & GP", Ministry of Industry and Trade of Russia
- **Jesus Herrera (online),** Director of Drugs, Medicines, and Cosmetics, Autonomous Health Control Service, Venezuela
- **Naala Grivapsh,** Corporate Quality Director, Binnopharm Group
- **Roman Karasyov,** Chief Qualified Person for Quality, Gedeon Richter-Rus
- **Faiza Yagudina,** Quality Director, Akrikhin
- **Vyacheslav Goryachkin,** Advisor on quality issues, technology transfers, Skopinfarm LLC
- **Ali Al-Muhsin (online),** Senior Products and Facilities Inspection Expert, Saudi Food and Drug Authority, Kingdom of Saudi Arabia

15:00–18:00
Small hall

Parallel Event

Session partner:
SUN Pharma

Masterclass for university professors on VR Technologies for Teaching the Industrial Technology of Medicines, with the issuance of certificates

The participants of the master class will be able to get acquainted with the opportunities of the simulation training complex "Virtual Factory for Universities", developed by the Eurasian Academy of Good Practices in cooperation with the State Institute of Medicines and Good Practices. The innovative VR product is intended for students in pharmaceutical, biotechnological, and chemical fields to take an internship in industrial pharmacy. The complex contains unique licensed software and educational materials for teachers, including those who do not have experience in working for a pharmaceutical company.

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Masterclass facilitators:

- **Irina Spichak,** Executive Director of the Eurasian Academy of Good Practices, Doctor of Pharmacy, Professor
- **Lyubov Zasova,** Deputy Executive Director of the Eurasian Academy of Good Practices, Ph.D.

16:30-16:45 **Break**

16:45-18:30
Main hall

Parallel Event

Panel session
Pharmaceutical Engineering. The initial stages of acceptance and qualification as part of the validation lifecycle of systems and equipment. A look from the perspective of the requirements of GMP Appendix No. 15 and industry experience

Questions and topics for discussion:

— Practical Application of the principles of the ISPE Baseline Guide Vol 5: Commissioning & Qualification 2nd Edition
— The relation of the various stages of qualification in the V-shaped model of the "life cycle" of validation
— URS as a "reference point" for validation activities
— Importance of the DQ stage for new and reconstructed systems; application of risk analysis at the DQ stage taking into account the provisions of the updated version of the ICH guideline Q9 (R1)

Moderator:

- **Vladimir Orlov*,** Director of the Eurasian branch of ISPE - MAFI EAEU

Speakers:

- **Alexander Belinsky,** Technical Director, PQE CIS
- **Ivan Moiseyev,** Head of the Validation Division, Geropharm LLC
- **Oleg Spitsky,** Chief of the Quality System, Biopharmproject LLC
- **Svetlana Skorik,** Quality Director, Polysan LTD

Front-row experts:

- **Natalia Burlakina,** Deputy Head of the Expertise Division of the FSI "SID & GP" of the Ministry of Industry and Trade of Russia
- **Vladimir Smirnov,** Deputy Head of the Pharmaceutical Inspectorate Cooperation Division, FSI "SID & GP" of the Ministry of Industry and Trade of Russia

SEPTEMBER 29, 2023

9:00–10:00 **Registration of participants, welcome coffee**

10:00–12:30 *Main hall*

Master Class. Part 1 (Theory) Most Frequent Non-Conformities. Experience of Pharmaceutical Inspectorates of Various Countries

Questions and topics for discussion:

— Typical non-conformities found during pharmaceutical inspections of the member states of the Eurasian Economic Union
— Experience of other countries' pharmaceutical inspectorates

Moderators:

- **Madina Sottaeva,** Head of Pharmaceutical Manufacturing Inspection Department of the FSI "SID & GP" of the Ministry of Industry and Trade of the Russian Federation
- An official of a regulatory authority of the EAEU country*

Speakers:

- **Mkrtych Shakaryan (online),** Head of the Department of Good Pharmaceutical Practice, CJSC "Scientific Center for Expertise of Drugs and Medical Technologies named of Academician Emil Gabrielyan"
- **Alena Launik*,** Head of the Department of Pharmaceutical Inspection of the Main Department for Control of Medical Activities and Circulation of Medicines of the Ministry of Health of the Republic of Belarus
- **Farida Makeyeva (online),** Head of the Inspection Department of the National Center for the Examination of Medicines and Medical Devices of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan
- **Chynarkul Kulova,** Chief Specialist of the Good Pharmaceutical Practices Division, Department of Pharmaceuticals and Medical Devices Supply, Ministry of Health of the Kyrgyz Republic
- **Nadezhda Arkhipova,** Deputy Head of the Pharmaceutical Manufacturing Inspection Department, FSI "SID & GP", Ministry of Industry and Trade of Russia
- **Jesus Herrera (online),** Director of Drugs, Medicines, and Cosmetics, Autonomous Health Control Service, Venezuela
- **Nani Handayani (online),** Head of Quality Management System Team, Directorate for Drug, Narcotics, Psychotropics, an Precursor Production Control, Indonesian Food and Drug Authority
- **Fatemeh Bashokouh,** Head of the Inspection Office, Iran Food and Drug Administration (IFDA)
- **Isaac Quiñones Maya (online),** Head of Inspection Team, Center for State Control of Medicines and Medical Devices (CECMED), Cuba

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- **Tania Zenaida Oviedo Latorre,** Specialist in Quality Management of Pharmaceutical Products – GMP Inspector, Directorate General of Medicines, Supplies and Drugs, Peru
- **Milton Eduardo Zambrano Masache (online),** General Technical Coordinator for Certification, National Agency for Regulation, Control and Sanitary Surveillance (ARCSA), Ecuador

Participants of the discussion:

- Representatives of pharmaceutical companies

12:30 – 14:00 **Lunch break**

14:00-16:00
Main hall
Master Class. Part 2 (Practice)
Interactive Part – Our Game GMP Quiz

16:00-16:30
Main hall
Summing Up the Results of the GMP Quiz. Winners Award Ceremony. Conference Close-Out

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