MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

GXP SID&GP

GMP IX PAN-RUSSIAN GMP CONFERENCE

PROGRAM of the 9th Pan-Russian GMP Conference with International Engagement

GMP: Continuous Improvement in Pharmaceutical Industry

August 21-23 2024,
Ufa
Toratau Congress Hall

August 21, 2024

08:30 – 09:30 **Registration and Coffee**

09:30 – 12:00
Concert Hall

Plenary session
Development Trends of Pharmaceutical Regulatory System
Panel 1

Questions and topics for discussion:

- Tools for strengthening regulatory systems
- Regulatory reliance: benefits and pitfalls. International experience.
- Isolation of regulatory systems: deterrence or decrease of dependency on external challenges
- Should the regulatory system remain flexible? To what extent?
- Regulatory system readiness to ensure access to medicinal products
- Development of local production to ensure safety of medicinal products
- Development strategy for production of novel drugs

Moderators :

- Elena Denisova, Deputy Director, Department of Pharmaceutical and Medical Industry Development, Ministry of Industry and Trade of Russia
- Vladislav Shestakov, Director, FSI "SID & GP"

Speakers:

- Dorina Pirgari, Technical Officer AMP/CPS, WHO EURO
- Natalia Volovich, Head, Marketing Authorization Department, Gedeon Richter, JSC
- Dmitry Galkin, Head, Department of Pharmaceutical and Medical Industry Development, Ministry of Industry and Trade of Russia
- Aisylu Kamaletdinova, Deputy Director, Department of Drug Supply and Regulation of Circulation of Medical Devices, Ministry of Health of the Russian Federation
- Valentin Pavlov, Doctor of Medical Sciences, Professor, Academician of the Russian Academy of Sciences, Rector, Bashkir State Medical University
- Dmitry Zaitsev, Chief Executive Officer, Pharmstandard, JSC
- Ali Mrabet, Minister of Health, Tunisia
- Bayu Wibisono, Director for Drugs, Narcotics, Psychotropics, and Precursors Production Control, Indonesian Food and Drug Authority (BPOM)
- Lisette Pérez Ojeda, Advisor, Center for State Control of Medicines and Medical Equipment of the Ministry of Public Health (CECMED), Cuba
- Ranga Chandrashekhar, Joint Drugs Controller, Central Drugs Standard Control Organisation (CDSCO), India

12:00 – 12:30 Coffee and Networking Break

August 21, 2024

12:30 – 14:00
Concert Hall

Plenary session
Development Trends of Pharmaceutical Regulatory System
Panel 2

Questions and topics for discussion:

- Regional unions - advantages and disadvantages for manufacturers of medicinal products
- EAEU Common Market for Medicinal Products turned 10 years old: results and perspectives
- Foreign pharmaceutical market access
- Role of regulatory convergence between different countries in overcoming trade barriers

Moderators :

- Elena Denisova, Deputy Director, Department of Pharmaceutical and Medical Industry Development, Ministry of Industry and Trade of Russia
- Vladislav Shestakov, Director, FSI "SID & GP"

Speakers:

- Avazbek Ibragimov, Deputy Director, State Unitary Enterprise "Center for Good Practices" of the Agency for the Development of the Pharmaceutical Industry, Uzbekistan
- Carolyn P. Custodio, Regional Supervisor, Food and Drug Administration, Philippines
- Chinara Mambetalieva, Deputy Director, EEC Technical Regulation and Accreditation Department
- Myo Zar Ni Saw, Director, Department of Food and Drug Administration, Myanmar
- Maksim Petrov, Trade Representative of Russia in Nigeria
- Konstantin Ryzhnikov, Department of Pharmaceutical and Medical Industry Development, Ministry of Industry and Trade of Russia
- Stanislav Uiba, Latin-American Institute of Biotechnology MECHNIKOV, S.A.
- Hossain Mohammad Imran, Assistant Director, Directorate General of Drug Administration (DGDA), Bangladesh
- Francisco Roger Urcuyo Garcia, Director, Quality Control Laboratory for Medicinal Products, Nicaragua
- Prof. Mojisola C. Adeyeye, Director General of National Agency for Food and Drug Administration and Control (NAFDAC)
- Cecilia Martínez Rossi, Director, General Directorate of Inspection, Ministry of Public Health, Uruguay

14:00 – 15:00 Lunch break

August 21, 2024

15:00 – 16:30
Concert Hall

Parallel Event

Session partner:
PRO.MED.CS Praha a. s.

Panel Discussion
Pharmaceutical Industry Interactions: From Science to Patient

Questions and topics for discussion:
- Interagency interaction in regulation of medicinal products
- Communication between the regulator, science and industry

Moderator:
Dmitry Somov, Director, FGBU "Information and Methodological Center for Examination, Accounting and Analysis of Circulation of Medical Products", Federal Service for Surveillance in Healthcare (Roszdravnadzor)

Speakers:
- Pavel Burenkov, Head, Department of Analysis and Project Management for Medicines, Center for Transfer of Medical Technologies, Federal State Budgetary Institution 'Scientific Centre for Expert Evaluation of Medicinal Products', Ministry of Health of the Russian Federation (FSBI 'SCEEMP')
- Elena Denisova, Deputy Director, Department of Pharmaceutical and Medical Industry Development, Ministry of Industry and Trade of Russia
- Kira Zaslavskaia, Director for New Products, Promomed
- Elena Kudriavtseva, Head, Center for Regulatory Interaction and Control, Deputy Director General, FGBU "Information and Methodological Center for Examination, Accounting and Analysis of Circulation of Medical Products", Federal Service for Surveillance in Healthcare (Roszdravnadzor)
- Aleksei Pavlov, Director, Nanolek
- Diana Chizhova, Head, Marketing Authorization Division, Department of Regulation of Medicinal Products and Medical Devices, Ministry of Health of the Russian Federation

15:00 – 16:30
Conference Hall 2

Parallel Event

Session partner:
Nacimbio

Interactive educational intensive class
Current aspects of conducting GMP self-inspection at pharmaceutical companies

Questions and topics for discussion:
- APS for aseptic process validation
- Elimination of system deficiencies caused by lack of time synchronization in production
- Data integrity management for laboratory equipment
- Equipment management process audit as a tool for identification of system errors in a production laboratory
- System errors when handling validation and qualification

Moderator:
Irina Spichak, Executive Director, Eurasian Academy of Good Practices, Doctor of Pharmaceutical Sciences, Professor

August 21, 2024

Speakers:

- Maksim Ablov, Head, GXP Audit Training Center, Eurasian Academy of Good Practices
- Tatiana Viazmina, Quality Director, R-Pharm
- Polina Gremiyakova, Director, Center for Metrology and Consulting "Poverie"
- Ekaterina Rastoltseva, Quality Director, NovaMedika
- Iagudina Faiza, Quality Director, Akrikhin

16:30 – 17:00 Coffee and Networking Break

17:00 – 18:00 **Master Class**
BUSINESS GAME: Qualified persons

19:30 – 22:00 **Evening Reception and Informal Networking**
by invitation

August 22, 2024

09:00 – 09:30

Registration and Coffee

09:30 – 11:00
Conference room

Session partner:
Promomed

Panel Discussion
EAEU Common Market for Medicinal Products turned 10 years old: results and perspectives

Questions and topics for discussion:

- Harmonization of national legislation on pharmaceutical inspections with the EAEU laws
- Initiation of inspection within the framework of marketing authorization procedure

Moderator:

Elena Denisova, Deputy Director, Department of Pharmaceutical and Medical Industry Development, Ministry of Industry and Trade of Russia

Speakers:

- Nazi Abdyrasulova, Head, Division of Good Pharmaceutical Practice, Department of Drug Provision and Medical Equipment, Ministry of Health, Kyrgyzstan
- Anni Galdunts, Head, Good Pharmaceutical Practice Department, Center of Drug and Medical Technology Expertise, Armenia
- Gelena Grosheva, Head, Division of Licensing and Inspection of the Production of Medicines, Ministry of Industry and Trade of Russia
- Vadim Kalinichenko, Department for Regulation of Medicines and Medical Devices, Ministry of Health of the Russian Federation
- Alena Launik, Deputy Head of Office, Pharmaceutical Inspection Department, Ministry of Health of the Republic of Belarus
- Chinara Mambetalieva, Deputy Director, EEC Technical Regulation and Accreditation Department
- Zhanar Ordabekova, Head, Department of Pharmaceutical Inspectorate and Integration, Ministry of Health of the Republic of Kazakhstan
- Dmitriy Rozhdestvenskiy, Head, Section of Coordination of Activities in the Sphere of Circulation of Medicines and Medical Products
- Madina Sottaeva, Head, Pharmaceutical Manufacturing Inspection Department, FSI "SID & GP"
- Dmitry Somov, Director, FGBU "Information and Methodological Center for Examination, Accounting and Analysis of Circulation of Medical Products", Federal Service for Surveillance in Healthcare (Roszdravnadzor)
- Tatsiana Tumelia, Head, Republican Control and Analytical Laboratory, Republican Unitary Enterprise "Center for Examinations and Tests in Health Service", Belarus

August 22, 2024

- Diana Chizhova, Head, Marketing Authorization Division, Department of Regulation of Medicinal Products and Medical Devices, Ministry of Health of the Russian Federation
- Vladislav Shestakov, Director, FSI "SID & GP"

11:00 – 11:15 Technical Break

11:15 – 12:15
Conference Hall 2

Parallel Event

Panel Session
Advisory Board. Coverage of Activities of Working Groups

Questions and topics for discussion:
- Part IV – GMP Requirements for Advance Therapy Medicinal Products (ATMPs)
- Annex 1 Production of Sterile Products. Legal Aspect: Contamination Control Strategy at the Enterprise
- Draft Guidance on Environmental Monitoring in Production Areas
- Scientific toxicological evaluation data to confirm the feasibility of manufacture of different medicinal products in shared facilities
- Qualified persons. The EAEU Association of Qualified Persons
- Current projects of the Working Group Pharmaceutical Engineering

Moderator:
Madina Sottaeva, Head, Pharmaceutical Manufacturing Inspection Department, FSI "SID & GP", Chairperson, Advisory Board

Speakers:
- Nadezhda Arkhipova, Deputy Head, Pharmaceutical Manufacturing Inspection Department, FSI "SID & GP"
- Natalia Burlakina, Deputy Head of the Expertise Division of the FSI "SID & GP"
- Liudmila Guzevatykh, Head, GMP Processes Toxicology, R-Pharm Group
- Olga Maklakova, Quality Director, Akrikhin
- Igor Falkovskiy, General Director Advisor for Pharmaceutical Projects, Tse-Tech, LLC
- Asia Cherniavskaia, Head, Testing center for quality control of medicines, IC ML -STANDARD, LLC

11:15 – 12:15
Concert Hall

Parallel Event

Session partner:
PHARMSTANDARD

Panel Session
Manufacture of biological medicinal products

Questions and topics for discussion:
- Advanced Therapy Medicinal Products (ATMPs) and Biomedical Cellular Products (BCPs); expert and manufacturer opinions
- Experience in development and manufacture of products derived from human blood

August 22, 2024

Moderator:
Elena Denisova, Deputy Director, Department of Pharmaceutical and Medical Industry Development, Ministry of Industry and Trade of Russia

Speakers:
- Denis Baranovsky, Head, Scientific and Production Facility of Biotechnology, FSBI "NMIC of Radiology", Ministry of Health of the Russian Federation, Candidate of Medical Sciences
- Vadim Merkulov, Deputy Director General, Evaluation of Medicinal Products, Federal State Budgetary Institution 'Scientific Centre for Expert Evaluation of Medicinal Products', Ministry of Health of the Russian Federation (FSBI 'SCEEMP')
- Mikhail Nureyev, Head, Plasma Projects Implementation Department, Pharmstandard, JSC
- Aleksandr Obukhov, Director, Department of Medicines, Pharmstandard, JSC
- Ivan Semenov, Deputy General Director, Skopinpharm

Speakers of the first row:
- Natalia Burlakina, Deputy Head of the Expertise Division of the FSI "SID & GP"
- Alena Launik, Deputy Head of Office, Pharmaceutical Inspection Department, Ministry of Health of the Republic of Belarus

12:15 – 12:45 Coffee and Networking Break

12:45 – 14:15
Concert Hall

Panel Session
Manufacturing Authorization: Control in Manufacturing, Expectations of a Regulatory Authority

Questions and topics for discussion:
- Manufacturing authorization - from preparing documents to obtaining a manufacturing authorization/ GMP certificate
- Passing the periodic assessment of compliance with the manufacturing authorization requirements; initial results
- Experience with passing the periodic assessment of compliance with the manufacturing authorization requirements (pharmaceutical companies)
- Audit of suppliers of raw materials, materials, and services

Moderator:
Elena Denisova, Deputy Director, Department of Pharmaceutical and Medical Industry Development, Ministry of Industry and Trade of Russia

August 22, 2024

Speakers:

- Elena Gaskarova, Deputy Head, Division of Licensing and Inspection of the Production of Medicines, Ministry of Industry and Trade of Russia
- Gelena Grosheva, Head, Division of Licensing and Inspection of the Production of Medicines, Ministry of Industry and Trade of Russia
- Tatiana Zagumennikova, Quality Director, Pharmstandard, JSC
- Iagudina Faiza, Quality Director, Akrikhin
- Mikhail Pavlov, Deputy Head, Division of Licensing and Inspection of the Production of Medicines, Ministry of Industry and Trade of Russia
- Dmitry Somov, Director, FGBU "Information and Methodological Center for Examination, Accounting and Analysis of Circulation of Medical Products", Federal Service for Surveillance in Healthcare (Roszdravnadzor)

14:15 – 15:00 Lunch break

15:00 – 16:30
Concert Hall

Parallel Event

Panel Session
Approaches to the Development of Quality System

Questions and topics for discussion:

- Maturity Level of Pharmaceutical Quality System
- Maintaining corporate quality assurance: experience of local and foreign manufacturers

Moderators:

- Nadezhda Arkhipova, Deputy Head, Pharmaceutical Manufacturing Inspection Department, FSI "SID & GP"
- Elena Arkova, Deputy General Director, Quality Section, BIOCAD

Speakers:

- Elena Arkova, Deputy General Director, Quality Section, BIOCAD
- Naala Grivapsh, Corporate Quality Director, Binnopharm Group LLC
- Carmen Rosa Quinte Rojas, Pharmaceutical Chemist Inspector, General Directorate of Medicines, Supplies and Drugs, Ministry of Health of Perú
- Miloš Luburić, GMP Inspector, Institute for Medicines and Medical Devices of Montenegro
- Mohammad Abdelnaeim Salem Qutob, Manager, Local Pharmaceutical Industry Development Unit, Egyptian Drug Authority (EDA)
- Ekaterina Nikiforova, Corporate Quality Director, JSC Pharmasyntez
- Inna Rozhkova, Association of International Pharmaceutical Manufacturers
- Yulia Chernyaeva, Head, Quality Department, GEROPHARM
- Vinay Kumar Gupta, Assistant Drugs Controller, Central Drugs Standard Control Organisation (CDSCO), India

August 22, 2024

15:00 – 16:30
Conference Hall 2

Parallel Event

Panel Session
ISPE does not only mean pharmaceutical engineering

Questions and topics for discussion:

- Concept Paper on the revision of EU GMP, Annex 11: prerequisites, expected changes and their interpretation
- ICH Q19 (R1) – the new ICH Q9 (R1) Guideline on Quality Risk Management. Review of related ICH guidelines and training materials
- Review of the new ISPE Baseline Guide Vol: Pharma 4.0 1st Edition. From Theory to Practice
- Ongoing Process Verification as part of the requirements of Annex 15 to the EAEU GMP

Moderator:
Vladimir Orlov, Director, Eurasian Union ISPE Affiliate

Speakers:

- Alexander Belinsky, Technical Director, PQE CIS
- Tatiana Viazmina, Quality Director, R-Pharm
- Igor Falkovskiy, General Director Advisor for Pharmaceutical Projects, Tse-Tech, LLC
- Kirill Futysh, Deputy Head, Validation Department, Generium JSC

Speaker of the first row:

- Natalia Burlakina, Deputy Head of the Expertise Division of the FSI "SID & GP"

16:30 – 16:45 Technical Break

16:45 – 18:00
Concert Hall

Parallel Event

Master Class (business game)
Manufacturing Authorization

16:45 – 18:00
Conference Hall 2

Parallel Event

Panel Discussion
Current approaches to preclinical and clinical trials of medicinal products

Questions and topics for discussion:

- Translational crisis in biomedical research and ways to overcome It
- Methodology for searching for promising drug candidates based on individual substances of plant origin
- Modern concepts of the Life Sciences industry. Life cycle of drugs.
- Development of deubiquitinating products as cardioprotectors in myocardial ischemia-reperfusion injury

August 22, 2024

- The role of genetics in the search for drug targets and development of new drugs
- Thietane-containing 1,2,4-triazoles - a promising class of biologically active substances
- Study of the interaction of pyrazole derivatives with proteins of the central nervous system in silico

Moderators:

- Valentin Pavlov, Professor, Academician of the Russian Academy of Sciences, Rector, Bashkir State Medical University
- Mikhail Galagudza, PhD, Professor, Corresponding Member of the Russian Academy of Sciences, Director, Institute of Experimental Medicine
- Vladimir Luzhanin, Rector, Perm State Pharmaceutical Academy, Candidate of Biological Sciences

Speakers:

- Mikhail Galagudza, PhD, Professor, Corresponding Member of the Russian Academy of Sciences, Director, Institute of Experimental Medicine
- Irina Gilyazova, Candidate of Medical Sciences, Head, Laboratory of Molecular Genetics, Bashkir State Medical University
- Alexander Samorodov, Professor, Head, Department of Pharmacology, Federal State Budgetary Educational Institution of Higher Education, Bashkir State Medical University
- Linara Bashirova, Candidate of Medical Sciences, Associate Professor, Department of Pharmacology, Federal State Budgetary Educational Institution of Higher Education BSMU of the Ministry of Health of Russia
- Galina Rozit, Candidate of Pharmaceutical Sciences, Head, Laboratory on search of small targeted molecules, Bashkir State Medical University
- Maksat Urazbaev, Candidate of Pharmaceutical Sciences, Laboratory on search of small targeted molecules, Bashkir State Medical University

August 23, 2024

09:00 – 10:00 **Registration and Coffee**

10:00 – 12:30
Concert Hall

Master Class. Part 1 (Theory)

Questions and topics for discussion:

- Most frequent non-conformities. Experiences of different foreign inspectorates

Moderator:

- Natalia Burlakina, Deputy Head of the Expertise Division of the FSI "SID & GP"

Speakers:

- Vivek Gill, Drugs Inspector, Central Drugs Standard Control Organisation (CDSCO), India
- Wissem Achour, Sub-Director of Inspections, National Agency for Pharmaceutical Products, Algeria
- Carmen Rosa Quinte Rojas, Pharmaceutical Chemist Inspector, General Directorate of Medicines, Supplies and Drugs, Ministry of Health of Perú
- Anni Galdunts, Head of Good Pharmaceutical Practice Department, State Non-Profit Organization, Scientific Centre of Drug and Medical Technology Expertise, Armenia
- Abdurovis Kabirov, Head, State Unitary Enterprise "Center for Good Practices" of the Agency for the Development of the Pharmaceutical Industry
- Alena Launik, Deputy Head of Office, Pharmaceutical Inspection Department, Ministry of Health of the Republic of Belarus
- Gulnar Narkabulova, Head, Pharmaceutical Inspectorate Department, National Center for Expertise of Medicines, Kazakhstan
- Maria Mercedes Bocansaca Cabrera, Zonal Analyst, National Agency for Regulation, Control and Sanitary Surveillance (ARCSA), Ecuador
- Said Farzullayev, Head, Pharmaceutical Track and Trace Department, Analytical Expertise Center, Ministry of Health, Azerbaijan
- Wang Lijie, GMP Inspector, Center for Food and Drug Inspection of NMPA, China

12:30 – 14:00 Lunch break

14:00 – 16:00
Concert Hall

Master Class. Part 2 (Hands on).
Interactive part: GMP Quiz

16:00 – 16:30
Concert Hall

Summing up the results of the GMP Quiz. Winner's reward ceremony. Closing the event

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Pharmstandard

Strategic partner

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Health is our mission

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Техносуверен
Информационный портал, освещающий новости технологического суверенитета России

ФЕДЕРАЛ ПРЕСС

СТАНДАРТЫ И КАЧЕСТВО

ИНФАРМ

ХИМИЧЕСКИЙ ЭКСПЕРТ
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БСТ

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Фарма РФ

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