MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

SID & GP

**PROGRAM DRAFT * ***

# 10th Pan-Russian GMP Conference with International Engagement

September 15-17, 2025
1 Ramenskiy Boulevard, Lomonosov Cluster, Moscow

REGULATION TODAY: STABILITY TOMORROW

# Monday, September 15, 2025

**9:30 – 11:00** Registration and Morning Coffee

**11:00 – 13:00**

## Parallel session
## Molecule Hall

### *EAEU broad market of medicinal products for human use*

- EAEU broad market of medicinal products;
- Key aspects of conducting inspections of domestic and foreign manufacturing facilities;
- GMP inspections and marketing authorization;
- Risk-based approach to inspection planning;
- Answers on GMP inspection questions from pharma industry.

Moderator:

**Dmitry Galkin**
Director, Department of Pharmaceutical and Medical Industry Development of the Ministry of Industry and Trade of the Russian Federation

Speakers:

**Vladislav Shestakov**
Director, FSI «SID & GP», Russia»

**Chinara Mambetalieva**
Deputy Director, EEC Technical Regulation and Accreditation Department

**Dmitriy Rozhdestvenskiy**
Head, Section of Coordination of Activities in the Sphere of Marketing of Medicines and Medical Products, EEC Technical Regulation and Accreditation Department

**Tatevik Yeritsyan**
Coordinator for Circulation of Medicinal Products and Medical Devices within the EAEU, State Non-Commercial Organization "Center for Expert Evaluation of Medicinal Products and Medical Technologies" of the Republic of Armenia

**Alena Launik**
Head, Pharmaceutical Inspection Directorate, Ministry of Health of the Republic of Belarus

**Zhanar Ordabekova**
Head, Directorate of Pharmaceutical Inspectorate and Integration, Ministry of Health of the Republic of Kazakhstan

**Nazi Abdyrasulova**
Head, Good Pharmaceutical Practices Department, Ministry of Health of the Kyrgyz Republic

**Elena Denisova**
Deputy Director, Department of Pharmaceutical and Medical Industry Development, Ministry of Industry and Trade of the Russian Federation

## Parallel session
## Atom hall

### *EAEU broad market of medicinal products for veterinary use*

- Review of legislation in the field of veterinary drug production;
- Key control issues at all stages of manufacture;
- Answers on GMP inspection questions from pharma industry.

Moderator:

**Timur Chibilyaev**
Executive Director, National Veterinary Association

Speakers:

**Maria Novikova**
Director, Veterinary Department of the Ministry of Agriculture of the Russian Federation

**Vladimir Subbotin**
Deputy Director, Department of Sanitary, Phytosanitary and Veterinary Measures of the Eurasian Economic Commission

**Anna Babushkina**
Deputy Head, Department of State Veterinary Surveillance, Federal Service for Veterinary and Phytosanitary Surveillance

**Danil Rudnyaev**
Advisor to the Director, Federal State Budgetary Institution "The Russian State Center for Animal Feed and Drug Standardization and Quality", Russia

**Olga Sorochinskaya**
Head, Quality Assurance Department, Federal State Enterprise "Stavropol Biofactory"

**Semen Zhavoronkov**
Executive Director, Association of Veterinary Pharmaceutical Manufacturers

**Timur Chibilyaev**
Executive Director, National Veterinary Association

# Monday, September 15, 2025

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| **11:00 – 13:00** | Mid-level speakers:<br><br>Gelena Grosheva<br>Head, Department of Licensing of the Manufacturing of Medicinal Products and Pharmaceutical Inspectorate quality assurance Ministry of Industry and Trade of the Russian Federation<br>Madina Sottaeva<br>Head, Department of Pharmaceutical Manufacturing Inspection, FSI "SID & GP, Russia | |
| **13:00 – 14:00** | Networking Lunch Break | |
| **14:00 – 15:30** | **Plenary Session**<br>**Molecule Hall**<br><br>*Pharmaceutical industry:*<br>*Joining forces for patients' health*<br><br>Moderator:<br><br>**Vladislav Shestakov, Director, FSI «SID & GP»**<br><br>Participants:<br><br>· **Anton Alikhanov,**<br>Minister of Industry and Trade of the Russian Federation<br><br>· **Mikhail Murashko,**<br>Minister of Health of the Russian Federation<br><br>· **Maksim Uvaydov,**<br>**State Secretary, Deputy Minister,**<br>**Ministry of Agriculture of the Russian Federation**<br><br>· **Anatoliy Garbuzov,**<br>Minister of the Government of Moscow, Head of the Department of Investment and Industrial Policy of the City of Moscow<br><br>· **Aleksey Repik,**<br>Chairman of ALL-Russian non-governmental organization «Business Russia»<br><br>· **Vsevolod Tkachuk,** Acting Director, Medical Scientific and Educational Institute of Lomonosov Moscow State University | |
| **15:30 – 16:00** | Networking Coffee Break | |

REGULATION TODAY: STABILITY TOMORROW

# Monday, September 15, 2025

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| **16:00 – 18:00** | **Molecule Hall**<br>*Manufacturing authorization of medicinal products for human use*<br><br>· Collaboration between the manufacturer and regulatory authority during the manufacturing authorization process;<br>· GMP inspection experience, feedback from pharma companies;<br>· Q&A Panel.<br><br>Moderator:<br><br>Elena Denisova<br>Deputy Director, Department of Pharmaceutical and Medical Industry Development, Ministry of Industry and Trade of the Russian Federation<br><br>Speakers:<br><br>Gelena Grosheva<br>Head, Department of Licensing of the Manufacturing of Medicinal Products and Pharmaceutical Inspectorate quality assurance Ministry of Industry and Trade of the Russian Federation<br>Dmitriy Somov<br>Acting General Director, Federal State Institution "IMCEAACMP" of Roszdravnadzor<br>Gorav Kumar<br>Deputy Chief Pharmaceutical Controller, Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Government of the Republic of India<br>Svetlana Skorik<br>Quality Director, Scientific & Technological Pharmaceutical Company Polisan LLC<br>Faiza Yagudina<br>Quality Director, Akrikhin JSC<br>Roman Karasev<br>Quality Director, Gedeon Richter Rus |
| **19:00 – 21:00** | **Welcome Networking Reception** |

# Tuesday, September 16, 2025

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| **9:00 – 10:00** | Registration and Morning Coffee | |
| | Session in parallel<br>**Molecule Hall**<br>*Annex 1 is pending* | Session in parallel<br>**Atom Hall**<br>*Approaches to manufacture of medicinal products containing hazardous substances*<br><br>*Manufacture of Hazardous Medicinal Products* |
| **10:00 – 11:30** | · Contamination control strategy;<br>· Extractables and leachables;<br>· Key changes in the new Annex 1;<br>· Experience with the implementation of new Annex 1: objectives and challenges;<br>· Barrier Technologies to minimize microbial contamination;<br>· PUPSIT: implementation experience. | · Review of regulatory documents on hazardous substances;<br>· Groups of hazardous medicinal products. Practice of classifying medicinal products as hazardous. Methodological guidance on manufacture of medicinal products in shared production facilities based on scientific data from toxicological assessment. Application practice;<br>· Comprehensive assessment of cross-contamination risks for the facility by considering risk factors;<br>· Use of isolator and barrier technologies for the manufacture of medicinal products containing hazardous substances and ensuring the protection of personnel during the manufacture of hazardous medicinal products.<br>· Most frequent deficiencies. |

# Tuesday, September 16, 2025

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| | *Annex 1 is pending*<br><br>Moderator:<br><br>**Nadezhda Arkhipova**<br>Deputy Head, Department of Pharmaceutical Manufacturing Inspection, FSI «SID & GP», Russia<br><br>Speakers:<br><br>**Wayne Matheuw Müller**<br>Chair, GMP Technical Committee at AMRH (African Medicines Regulatory Harmonization)<br>**Vitaly Kazulkin**<br>Director of Quality Department, Geropharm<br>**Aleksandr Belinskiy**<br>Technical Director, PQE CIS<br>**Tatiana Vyazmina**<br>Quality Director, R-Pharm JSC group of companies | *Manufacture of Hazardous Medicinal Products*<br><br>Moderator:<br><br>**Gelena Grosheva**<br>Head, Department of Licensing of the Manufacturing of Medicinal Products and Pharmaceutical Inspectorate quality assurance Ministry of Industry and Trade of the Russian Federation<br><br>Speakers:<br><br>**Liudmila Guzevatykh**<br>Head, GMP Processes Toxicology Group, Quality Department, R-Pharm JSC<br>**Olga Maklakova**<br>Chimpharm JSC (SANTO) (Republic of Kazakhstan), Corporate Quality Director of Akrikhin JSC in the Eurasian Economic Zone<br>**Vera Golovushkina**<br>Quality Director, R-Opra LLC<br>**Georgy Derzskiy**<br>Deputy Head, Pharmaceutical Inspectorate Training and Development Department of FSI "SID & GP", Russia |
| **11:30 – 12:00** | Networking Coffee Break | |

# Tuesday, September 16, 2025

**12:00 – 13:30**

## Session in parallel
**Molecule Hall**

*Personnel are the greatest asset.*
*Competence requirements for key personnel*

- Regulatory requirements;
- Basic training program. Training of QPs responsible for manufacture and labeling;
- Continuous professional training program;
- Training for key personnel in the EAEU member states (Republic of Belarus, Republic of Kazakhstan, Republic of Armenia)
- Regulatory requirements;
- Basic training program for manufacturers of veterinary drugs.

Moderator:

**Elena Gaskarova**
Head, Department of Inspection of the Manufacturing of Medicinal Products and Compliance control with Mandatory Requirements, Ministry of Industry and Trade of the Russian Federation

Speakers:

**Irina Spichak**
Executive Director, Eurasian Academy of Good Practices, PhD in Pharmacy (Doctor's Degree), Professor

**Natalia Pyatigorskaya**
Head, Department of Industrial Pharmacy of the Federal State Autonomous Educational Institution of Higher Education, I.M. Sechenov First Moscow State Medical University of the Ministry of Health of the Russian Federation

**Farida Kayupova**
Head of the Department of Pharmacy, Kazakh-Russian Medical University, Republic of Kazakhstan, PhD in Pharmacy,

**Danil Rudnyaev**
Advisor to Director, Federal State Budgetary Institution "The Russian State Center for Animal Feed and Drug Standardization and Quality", Russia

**Yulia Chernyaeva**
Head of Corporate Quality, Geropharm

**Rimma Abramovich**
Head, Medical Scientific and Educational Center, Institute of Regenerative Medicine of the Moscow State University, Russia

## Session in parallel
**Atom Hall**

*Topical issues related to core activities of microbiology laboratories within pharmaceutical facilities*

- Designing microbiology laboratories;
- Essential equipment for microbiology laboratory: current upgrade issues;
- Contamination control strategy (microbiology);
- Digital transformation in environmental monitoring: interactive maps for environmental monitoring;
- Microbiological monitoring process: analysis of the clean room microbiome (including microbial identification, particularly, identification of local isolates)

Moderator:

**Asya Chernyavskaya**
Head, Testing Center ML-STANDART LLC

Speakers:

**Aleksei Topnikov**
Director, G.M. Project-Rus JSC

**Sergey Yakovlev**
Head, Bacteriological Laboratory at Ozon LLC

**Tatiana Vyazmina**
Quality Director, R-Pharm JSC group of companies

**Elena Izvekova**
Head, Microbiological Laboratory QC Dpt. at PharmFirm SOTEX

**Ilya Golubev**
Key Account Manager, Pharmaceutical Division at BioMérieux Rus LLC

**Evgeniya Yakusheva**
Head, Microbiological Laboratory at Velpharm-M (part of Velpharm-Group)

# Tuesday, September 16, 2025

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| **13:30 – 14:30** | Networking Lunch Break | |
| **14:30 – 16:00** | Session in parallel<br><br>**Molecule Hall**<br>*Regulation of ATMP local production in Russia: Open discussion*<br><br>· ATMPs today: legal framework, industrial prospects, and ways for local production;<br>· Identifying barriers and practical solutions for accelerated ATMPs integration into Healthcare systems;<br>· Improving the regulatory framework;<br>· Strategies to increase investment attractiveness of the ATMP sector. | **Insight session**<br>**Round table discussion**<br><br>**Atom Hall**<br>*Digital transformation in the pharmaceutical industry: How far away is the future?*<br><br>· Adoption of artificial intelligence. Digital Twins;<br>· Digital transformation and AI adoption: How will the regulation of marketing authorization and quality control of medicinal products change due to widespread adoption of AI at all stages of medicine lifecycle?<br>· AI in quality assurance and GxP systems: What should the industry and regulator be prepared for?<br>· Key trends and the future of AI regulation;<br>· 4th Industrial Revolution. Digital, Smart, Virtual Factories of the Future.<br>· Digital platforms. Digital Twins. |

# Tuesday, September 16, 2025

**14:30 – 16:00**

## *Regulation of ATMP local production in Russia: Open discussion*

Moderator:

**Irina Filatova**
State Duma Member, Head of the Expert Council for the Development of Competition in the Sphere of Pharmaceutical Activities under the State Duma Committee for the Development of Competition

Speakers and discussion participants:

**Igor Korobko**
Director, Department of Science and Innovative Development of Healthcare, Ministry of Healthcare of the Russian Federation

**Jorge Antonio Canales Pacheco**
Head, National Medicines Agency, Public Health Institute of Chile

**Natalia Burlakina**
Deputy Head, Department of Pharmaceutical Manufacturing Inspection, FSI "SID & GP, Russia

**Ekaterina Yakovleva**
Director, Medicines Registration Department, Russia and Eurasia, AstraZeneca

**Ilya Klabukov**
PhD in Biology, Regenerative Medicine Division, Center for Innovative Radiological and Regenerative Technologies, Federal Sate Budgetary Institution "National Medical Research Radiological Centre" of the Ministry of Health of the Russian Federation

Headline Speaker

**Elena Denisova**
Deputy Director, Department for Pharmaceutical and Medical Industry Development, Ministry of Industry and Trade of the Russian Federation

## *Digital transformation in the pharmaceutical industry: How far away is the future?*

Moderator:

**Elena Popova**
Senior Director for Regulatory Affairs and Healthcare, Association of International Pharmaceutical Manufacturers (AIPM)

Speakers:

**Dr. Meng Chen**
Vice President, Head of Biometrics and Data Science, AstraZeneca (China) (Online)

**Elena Arkova**
Deputy General Director for Quality, Biocad JSC

**Olga Maklakova**
Chimpharm JSC (SANTO) (Republic of Kazakhstan)
Director of Corporate Quality of the Eurasian Economic Zone, Akrikhin JSC

**Igor Sukhomlin**
Head, Technology Projects, Technical Directorate R-Pharm

**Michael Pelosi**
Lead, Quality Assurance, Analytics, Astellas (USA) (Online)

**Artur Kadurin**
Head, AI in Life Sciences Research Group, Artificial Intelligence Research Institute

**Ekaterina Kazakova**
Quality Director, PROMOMED

**16:00 – 16:30**

Networking Coffee Break

**16:30 – 17:30**

Master Class (business game)
Molecule Hall

*VR game*
*Identifying deficiencies using the VR plant project*

Moderators:

**Elena Gaskarova**
Head, Department of Inspection of the Manufacturing of Medicinal Products and Compliance control with Mandatory Requirements, Ministry of Industry and Trade of the Russian Federation

**Mikhail Pavlov**
Deputy Head, Medicinal Product Manufacture and Compliance Supervision Division, Department for Pharmaceutical and Medical Industry Development of the Ministry of Industry and Trade of the Russian Federation

# Wednesday, September 17, 2025

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| **9:00 – 10:00** | Registration and Morning Coffee |
| **10:00 – 12:00** | **Master Class. Part 1 (Theory)**<br>**Molecule Hall**<br>*GMP inspection*<br>**Most frequent deficiencies**<br><br>Moderators:<br>Madina Sottaeva<br>Head, Department of Pharmaceutical Manufacturing Inspection, FSI "SID & GP, Russia<br>Alena Launik<br>Head, Office for Pharmaceutical Inspection, Ministry of Health of the Republic of Belarus<br><br>Speakers:<br><br>Naira Eloyan<br>Head of Quality Control Laboratory, GMP inspector engaged in EAEU GMP in foreign countries, Center of Drug and Medical Technology Expertise, Armenia<br>Nazi Abdyrasulova<br>Head, Good Pharmaceutical Practices Department, Ministry of Health of the Kyrgyz Republic<br>Karina Maslovskaya<br>Head, Quality Assurance Department, the State Institution "State Pharmaceutical Supervision in the Sphere of Circulation of Medicines" Gosfarmnadzor ", Republic of Belarus<br>Natalia Burlakina<br>Deputy Head, Department of Pharmaceutical Manufacturing Inspection, FSI "SID & GP, Russia<br>Thi Lan Huong Nguyen<br>GMP Inspector, Drug Administration of Vietnam<br>Mahmoud Fawaz Sitan Al-Qawasmeh<br>Deputy Director of Drug Directorate, Head of Drug Control and Inspection, Hashemite Kingdom of Jordan<br>Muhammad Mawardi Bin Zakaria<br>Senior Principal Assistant Director, GMP Section, Centre of Compliance & Quality Control, National Pharmaceutical Regulatory Agency, Ministry of Health of Malaysia<br>Cecilia Martinez Rossi<br>Director of Inspection Department, Ministry of Public Health of Uruguay |
| **12:00 – 13:00** | Networking Lunch Break |
| **13:00 – 15:00** | **Master Class. Part 2 (Practice)**<br>*GMP inspection*<br>Business game for industry experts. Modeling cases that may surface during the inspections at a manufacturing facility<br>(Teams of 5+ people, with the participation of inspectors from the Ministry of Industry and Trade of Russia and FSI "SID & GP")<br>Moderators:<br><br>Nadezhda Arkhipova<br>Deputy Head, Department of Pharmaceutical Manufacturing Inspection, FSI "SID & GP", Russia<br>Anna Derkach<br>Head, Division of Inspection of Foreign Pharmaceutical Manufacturers, FSI "SID & GP", Russia |
| **15:00 – 16:00** | Closing Remarks |

* Speakers, discussion topics, timing and dates are subject to change

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ВЕТБИОПРОМ
НАЦИОНАЛЬНАЯ АССОЦИАЦИЯ

НАЦИОНАЛЬНАЯ ВЕТЕРИНАРНАЯ АССОЦИАЦИЯ