DRAFT

Programme of VAll-Russia GMP-Conference with international participation

«Common GxP Rules - Quality for the greater health»

September 30 – October 1, 2020

Day 1
(September 30, 2020)

Time (GMT +3)	
9:30 – 10:00	**Conference opening**
10:00 – 12:00	**Plenary session** **"Pharmaceutical and medical industry: lessons from the pandemic"** Issues to be discussed: ● Special conditions for the development, manufacturing, registration and further movement of new medicines during the pandemic ● Experience of industry and regulator under special conditions. Consolidation of joint work efforts ● Interagency interaction in the fight against coronavirus COVID-19 infection ● Intergovernmental program for the medicines manufacturing within the common Eurasian market in the context of the pandemic ● Preparedness of health systems for pandemic: world experience and the experience of the EAEU countries
12:00 – 12:15	Break
12:15 – 14:15	**Panel discussion** **"Present and future of the EAEU countries single market integration"** Issues to be discussed: ● The experience of the EAEU Member States' path of joining the PIC/S (Republic of Armenia) ● Balance of Eurasian and national requirements in the EAEU Member States (Republic of Armenia) ● Creation of integration mechanisms for implementation of the requirements within the EAEU single market functioning ● Pharmacopoeia standardization discussion issues: "Composite sample" and other problems of ambiguous interpretation of the OOS results in pharmacopoeia analysis ● Eurasian procedure of special drugs registration. Harmonization of registration procedure for radiopharmaceuticals ● Experience of undergoing inspections and registering medicinal products according to the EAEU rules *Session's partner - PRO.MED.CS Praha a.s.*
14:15 – 14:30	Break
14:30 - 16:00 Parallel event	**Panel discussion** **"Potential of API local manufacturing"** Issues to be discussed: ● Challenges of organizing global supply chains of pharmaceutical substances during the pandemic ● Development prospects of local manufacturing of a wide range of pharmaceutical substances in the Russian Federation ● Ways to overcome the dependence of the local pharmaceutical market on the raw materials supplies from the Southeast Asia

	• Main criteria for forming the government strategy for the development of national substances manufacturing • Manufacturing of reference samples • Issues of impurities indication in FPP (e.g. nitrosamines, sartans) *Session's partner – "Pharmasyntez" company*
14:30 - 16:00 Parallel event	**Roundtable discussion** **"The future of local pharmaceutical industry specialists"** Issues to be discussed: • Prospects for industrial practices in the training of students of the Faculty of Pharmacy • A distinctive role of continuing professional education during the pandemic. Effective mechanisms for personnel retraining and professional development • The Academy of Inspectorates as a resource for ensuring expert and narrowly specialized education in the field of GxP • Intellectual resources of pharmaceutical companies as a basis for innovative development and competitiveness on the market • Strategy of the leading Russian universities in the context of current challenges of the time
14:30 - 16:00 Parallel event	**Closed event** **"Meeting of Russian pharmaceutical manufacturers with Trade missions of the Russian Federation"** Issues to be discussed: • Experience of Russian Trade Missions in the framework of export strategy during the pandemic • Countries overview and market conditions • States' needs for pharmaceutical products PRE-REGISTRATION IS REQUIRED Participants: 1. Deputy Trade Representative - Viktor Sheremetker (Trade mission in Brasilia) 2. Chief expert - Vadim Dolgopolov (Trade mission in China) 3. Trade Representative – Artyom Tsinamdzgvrishvili (Trade mission in Morocco) 4. Trade Representative – Andrey Makarov (Trade mission in Netherlands) 5. Trade Representative – Rybas Alexander (Trade mission in India) 6. Trade Representative – Bogatyr Alexander and Leading expert –Baldin Sergey (Trade mission in Cuba)
14:30 - 16:00 Parallel event	**Roundtable discussion** **"Current trends in global legislation and global harmonization"** Issues to be discussed: • Role and responsibilities of marketing authorization holders from the perspective of modern GMP requirements. Topical issue and ways of resolving. Position of the EU regulatory authorities (EMA) • Main provisions of the new version of Annex draft No. 16 GMP EAEU from the point of view of the GMP requirements and the Qualified person job in pharmaceutical enterprise. • Approaches and methods for studying the medicines stability in the EAEU law

	• New European guidelines for water treatment quality: should the EAEU guidelines be updated? *Session's partner – PRO.MED.CS Praha a.s.*
16:00 – 16:15	Break
16:15– 17:45 Parallel event	**Roundtable discussion** **"Interdisciplinary approach for innovation and export potentials for the development of the EAEU pharmaceutical industry"** Issues to be discussed: • The place and meaning of the Good Laboratory Practice (GLP) Regulations in the "medicine life cycle" • GLP and bioequivalence studies: requirements for testing laboratories that perform bioanalytical (laboratory) studies of medicines • Peculiarities of the development and registration of medicines and the potential of local original medicines • Recognition of the local GLP regulation system at the international level. The model of effective GLP regulation from the perspective of Good Pharmaceutical Practices in the EAEU • GMP-evaluation of manufacturing facilities for clinical trials • Pre-registration expertise of Module 3 "Quality" set of documents • Relationship between GDP rules and licensing of pharmaceutical activities
16:15– 17:45 Parallel event	**Roundtable discussion** **"Continuous manufacturing"** Issues to be discussed: • ICH Q13 and technological solutions "continuous manufacturing" • Development of the ISPE EAEU. Prospects and challenges. • CM elements for oral solid dosage process • Case study. Development of CM for API manufacturing • CM from inspector's perspective *Session's partner – "Nanolek" company*
17:45 – 18:00	Break
18:00 – 18:20	Closing ceremony

Day 2
(October 1, 2020)

Workshop **"New formats of GMP-inspections"**	
Time (GMT +3)	
10:00 – 12:00	**"New formats of GMP-inspections: manufacturer's and regulator's views"** ● Regulatory framework and experience of inspecting pharmaceutical manufacturers for the compliance with GMP rules during the pandemic ● Exchange of experience with representatives of foreign pharmaceutical inspectorates *Session's partner – "Akrikhin" company*
12:00-12:15	Break
12:15 -14:15	Practical part: **"New formats of GMP-inspections: online inspection of the site manufacturing injection forms"** ● Experience in conducting pharmaceutical inspections. Analysis of typical non-conformities ● Movie-clip about the preparation of a site to be inspected ● Movie - online inspection of injection forms manufacturing ● Analysis of situational issues. Answers to questions ● Voting on identified non-conformities
14:15 – 14:30	Break
14:30 – 16:15	Practical part: **"New formats of GMP-inspections: undergo the inspection together with the regulator"** ● Online inspection ● Manufacturer's comments about remote GMP inspections ● Analysis of situational issues. Answers to questions *Session's partner – "Novo Nordisk" company*
16:15 - 16:30	Wrapping up
12:15 - 14:00	**Closed event** **"Meeting of Russian pharmaceutical manufacturers with Trade missions of the Russian Federation"** Issues to be discussed: ● Experience of Russian Trade Missions in the framework of export strategy during the pandemic ● Countries overview and market conditions ● States' needs for pharmaceutical products PRE-REGISTRATION IS REQUIRED Participants: 1. Trade Representative – Nickolai Aslanov (Trade mission in Egypt) 2. Trade Representative – Petr Pavlenko and Consultant – Alexandra Krasovskaya (Trade mission in Japan) 3. Trade Representative – Sergey Rossomakhov (Trade mission in Indonesia)

	4. Deputy Trade Representative – Aleksey Glinskiy and Consultant – Sergey Piskunov (Trade mission in South Africa) 5. Trade Representative – Galina Kurochkina (Trade mission in Spain) 6. Trade Representative – Nalich Ivan (Trade mission in Algeria) 7. Chief expert – Tsygankov Kirill (Trade mission in Vietnam) 8. Trade Representative – Makarov Mikhail and Consultant – Zabyrina Elena (Trade mission in France)