**Program draft**
VI All-Russia GMP Conference with international participation  
22–24 September 2021, Saint Petersburg  
Park Inn by Radisson Pribaltiyskaya Hotel & Congress Center

<table>
<thead>
<tr>
<th>22 September 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>9:00 – 10:00</strong></td>
</tr>
</tbody>
</table>
| **10:00 – 12:00** | Opening of the Conference  
Plenary session  
“Strong regulator – robust industry”  
**Questions and topics for discussion:**  
- Structural approach in bringing the Russian industry to an international level  
- Actions of the regulatory authorities during the pandemic.  
  Experience of inter-agency interaction.  
  Analysis of decisions made and their results  
- Experience of foreign drug regulatory authorities  
**Moderator:**  
- **Vladislav Shestakov**, Director of FSI “SID & GP” of the Russian Ministry of Industry and Trade  
**Speakers:**  
- Representative of the Russian Ministry of Industry and Trade  
- Representative of the Russian Ministry of Health  
- Representative of the Federal Service of Surveillance in Healthcare  
- Representative of the Eurasian Economic Commission  
- Representatives of the Eurasian Economic Union’s regulatory authorities  
- Representatives of the European Union’s regulatory authorities  
- Representative of the Russian Direct Investment Fund  
- Representatives of foreign drug regulators  
- Representatives of pharmaceutical companies and industry associations  |
| **12:00 – 12:20** | Break |
| **12:20 – 13:50** | Panel discussion  
“New elements in regulating drug circulation within the Eurasian Economic Union”  
**Questions and topics for discussion:**  
- Pressing issues pertaining to the integration within the single pharmaceutical market of the EAEU  
- Review of current changes in the laws and regulations  
- New level III documents  
- Inspection procedure in accordance with the EAEU rules (as part of the registration procedures and on the request of the national Ministry of Health) and regulators’ experience in conducting inspections of drug manufacturing  
- Issues regarding the maintenance of the EAEU register  
- Pharmacopeia of the Eurasian Economic Union |
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>13:50 – 14:50</td>
<td>Lunch</td>
</tr>
<tr>
<td>14:50 – 16:20</td>
<td>Continuation of panel discussion</td>
</tr>
<tr>
<td></td>
<td>“New elements in regulating drug circulation within the Eurasian economic union”</td>
</tr>
<tr>
<td>16:50 – 16:40</td>
<td>Break</td>
</tr>
<tr>
<td>16:40 – 18:10</td>
<td>Panel discussion</td>
</tr>
<tr>
<td></td>
<td>“Current developments of the pharmaceutical market: Time and place for systemic expertise”</td>
</tr>
</tbody>
</table>

**Questions and topics for discussion:**
- The need for enhancing systems of domestic pharmaceutical developments
- Compliance with GMP rules during the drug’s development phase
- Technology transfer. Scaling-up of manufacturing.
- Development of the domestic full manufacturing cycle: objectives, opportunities and perspectives
- System of state reference standards in Russia
- Main phases of drug development: active pharmaceutical substance, preclinical studies, clinical studies, registration, manufacturing

**Moderators:**
- Roman Ivanov, Rector of Sirius University of Science and Technology, Educational Foundation “Talent and Success”

**Speakers:**
- Representative of the Russian Ministry of Industry and Trade
- Representative of FSI “SID & GP” of the Russian Ministry of Industry and Trade
- Representative of LLC “National Centre of Reference Standards”
- Representatives of industry communities and associations
- Representatives of the pharmaceutical companies
<table>
<thead>
<tr>
<th>20:00</th>
<th>Evening event</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>23 September 2021</strong></td>
<td></td>
</tr>
<tr>
<td>9:00 – 10:00</td>
<td>Registration of participants</td>
</tr>
</tbody>
</table>
| 10:00 – 11:30 | Panel discussion  
“Holistic view pertinent to regulation of GxP practices”  
*Questions and topics for discussion:*  
- GLP regulatory issues: laboratories and testing centres  
- New regulatory elements in GCP  
- Legal and organization issues of GDP regulation  
- Dietary supplements: relevant regulatory issues  
*Moderators:*  
- *Roman Drai*, Director of R&D center, Geropharm  
- *Lillia Titova*, Executive Director Union of Professional Pharmaceutical Organizations (SPFO)  
*Speakers:*  
- Representative of the Russian Ministry of Industry and Trade  
- Representative of the FSI “SID & GP” of the Russian Ministry of Industry and Trade  
- Representative of the Russian Ministry of Health  
- Representatives of the Eurasian Economic Union member states  
- Representatives of R&D centers  
- Representatives of pharmaceutical companies  
- Representatives of industry associations, including association of the manufacturers of dietary supplements  
- Representatives of distribution companies |
| 11:30 – 11:50 | Break |
| 11:50 – 13:20 | Continuation of panel discussion  
“Holistic view pertinent to regulation of GxP practices” |
| 11:45 – 13:15 | Panel discussion  
“Inspection of manufacturers of drugs for veterinary use. Regulation and statistics. The view of the state and business”  
*Questions and topics for discussion:*  
- Regulation of inspection of manufacturers of drugs for veterinary use under EAEU rules  
- Experience of inspecting European manufacturers of veterinary drugs  
*Moderators:*  
- Under consideration  
*Speakers:* |
Panel discussion
“Regulatory issues pertinent to export of Russian drugs”

Questions and topics for discussion:
- Foreign markets review. Potential and opportunities of Russian pharmaceutical manufacturers for exporting their products
- Challenges and ways to overcome them in generating export opportunities for Russian companies: issues related to the compliance with international standards and requirements
- Preparation of the registration dossier
- Passing foreign GMP inspections. Experience of the leading Russian companies

Moderator:
- Dmitriy Galkin, Director of Department of Pharmaceutical and Medical Industry Development, Russian Ministry of Industry and Trade
- Chairman of the Association of Pharmaceutical Manufacturers of the Eurasian Economic Union

Speakers:
- Representative of the Russian Ministry of Industry and Trade
- Representative of FSI “SID & GP” of the Russian Ministry of Industry and Trade
- Trade representatives of the Russian Federation abroad
- Representatives of the pharmaceutical companies
- Representative of the European Union
- Representatives of the member-states of the Eurasian Economic Union

Break

Session of the General Sponsor

24 September 2021

10:00 – 11:00
1. Competition “Best Technical Director (Specialist)”
2. Launch of the voting on a video-clip contest
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:00 – 11:20</td>
<td>Break</td>
</tr>
<tr>
<td>11:20 – 12:35</td>
<td>Master-class</td>
</tr>
<tr>
<td></td>
<td>“Technology Transfer. Regulatory Requirements”. Part 1</td>
</tr>
<tr>
<td></td>
<td>Speakers:</td>
</tr>
<tr>
<td></td>
<td>• Representative of FSI “SID &amp; GP” of the Russian Ministry of Industry and Trade</td>
</tr>
<tr>
<td></td>
<td>• Representative of the Russian Ministry of Industry and Trade</td>
</tr>
<tr>
<td>12:35 – 13:35</td>
<td>Lunch</td>
</tr>
<tr>
<td></td>
<td>Termination of the voting on a video-clip contest</td>
</tr>
<tr>
<td>13:35 – 15:05</td>
<td>Master-class</td>
</tr>
<tr>
<td></td>
<td>“Technology Transfer. GMP Inspections. Practice of Technology Transfer from the inspector’s point of view”</td>
</tr>
<tr>
<td></td>
<td>Speakers:</td>
</tr>
<tr>
<td></td>
<td>• Representatives of FSI “SID &amp; GP” of the Russian Ministry of Industry and Trade</td>
</tr>
<tr>
<td></td>
<td>• Representatives of pharmaceutical companies</td>
</tr>
<tr>
<td></td>
<td>1. Summing up voting results of a video-clip contest, award ceremony</td>
</tr>
</tbody>
</table>