OUTSOURCER’S QUESTIONNAIRE

Please, provide objective answers to this questionnaire, as your answers will be used for preliminary assessment.

Specialists of FSUE SPbSRIVS FMBA of Russia guarantee confidentiality of all data contained in your answers.

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| --- | --- | --- | --- | --- |
| **1. Basic information on the company** | | | | |
| Full name |  | | | |
| Actual address |  | | | |
| Company address |  | | | |
| Telephone |  | | | |
| Company’s website |  | | | |
| Founded (year) |  | | | |
| 1. **2.Contact Information** | | | | |
| 2.1. Full Name of Enterprise Director | | | | |
| 2.2. Full Name and Position of Nominated Contact Person | | | | |
| Phone:  Fax: | | | | |
| E-Mail | | | |  |
| **3.Information on staff** | | | | |
| Total personnel | | | |  |
| Please attach an organization chart copy if possible | | Attached | Not attached | |
| **4. Types of services provided** | | | | |
| * Conducting preclinical trials * Conduct of clinical trials * Transportation, storage, distribution services * Services of contract laboratories for quality control of raw materials, APIs and MPs * Services for preparing clothes and mops for cleaning (washing, sterilization) * Contract manufacturing services (filling, packaging, release quality control, etc.) * Validation/qualification services * Inactive premises installation services; inactive premises panel system installation services * Pharmacovigilance services * Other services | | | | |
| 5. General information | | | | |

|  |  |  |
| --- | --- | --- |
| 5.1 Does your company have a license or other permit for the type of activity?  *Please attach the documents to the Questionnaire* | Yes | + 5 points |
| ☐ | 0 points |
| 5.2 Does your company have any other applicable certificates/licenses?  *Please attach the documents to the Questionnaire* | Yes | + 5 points |
| ☐ | 0 points |
| 5.3 Are any processes performed by subcontractors?  *If yes, please indicate what services and which companies provide them to you* | Yes | Not applicable |
| ☐ | Not applicable |
| 5.4 Do you have a procedure regulating the service provision? | Yes | + 5 points |
| ☐ | 0 points |
| 5.5 Does your company carry out customer satisfaction assessments? | Yes | + 5 points |
| ☐ | 0 points |
| 5.6 Is a training program developed for personnel involved in providing services? | Yes | + 5 points |
| ☐ | 0 points |
| 5.7 Has any procedure been drafted for management of documents and records? | Yes | + 5 points |
| ☐ | 0 points |
| 5.8 Are discrepancies being monitored? | Yes | + 5 points |
| ☐ | 0 points |
| 5.9 Are internal audits carried out? | Yes | + 5 points |
| ☐ | 0 points |
| **6. Service provider assessment by category** | | |
| **6.1 Contract manufacturing services**  (please cross out if not applicable) | | |
| 6.1.1 Do you have a quality policy and quality manual? | Yes | + 5 points |
| ☐ | 0 points |
| 6.1.2 Is a supplier/outsourcer assessment carried out? | Yes | + 5 points |
| ☐ | 0 points |
| 6.1.3 Are changes being managed? | Yes | + 5 points |
| ☐ | 0 points |
| 6.1.4 Is environmental monitoring carried out in production and storage areas? | Yes | + 5 points |
| ☐ | 0 points |
| 6.1.5 Have procedures for changing clothes by personnel been developed? | Yes | + 5 points |
| ☐ | 0 points |
| 6.1.6 Have equipment cleaning procedures been developed? | Yes | + 5 points |
| ☐ | 0 points |
| 6.1.7 Has a maintenance program been developed for equipment and utility systems? | Yes | + 5 points |
| ☐ | 0 points |
| 6.1.8 Has an equipment verification/calibration/qualification program been developed? | Yes | + 5 points |
| ☐ | 0 points |
| 6.1.9 Is there incoming inspection of raw materials/other materials, in-process control and finished product control? | Yes | + 5 points |
| ☐ | 0 points |
| 6.1.10 Does your company have a qualified person? | Yes | + 5 points |
| ☐ | 0 points |
| 6.1.11 Is your company ready to accept a physical (on-site) audit by FSUE SPbSRIVS FMBA of Russia? | Yes | + 5 points |
| ☐ | 0 points |
| 6.1.12 Is your company ready to enter into a Quality Agreement with FSUE SPbSRIVS FMBA of Russia? | Yes | + 5 points |
| ☐ | 0 points |
| **6.2 Services of contract laboratories for quality control of raw materials, APIs and MPs**  (please cross out if not applicable) | | |
| 6.2.1 Do you have a documented procedure for the receipt and distribution of samples received for analysis?  *Please specify the procedure* | Yes | + 5 points |
| ☐ | 0 points |
| 6.2.2 How does personnel enter the laboratory premises? Is access to the laboratory premises restricted?  *Please describe the process or attach the procedure. Are they attached?* | Yes | + 5 points |
| ☐ | 0 points |
| 6.2.3 Are the temperature and relative humidity monitored in the laboratory premises? | Yes | + 5 points |
| ☐ | 0 points |
| 6.2.4 Are there detailed records of tests, reflecting the results obtained and the equipment used (formulas, calculations, HPLC and GLC chromatograms, spectrograms, etc.)? | Yes | + 5 points |
| ☐ | 0 points |
| 6.2.5 Are there approved methods regulating the storage and testing of samples? | Yes | + 5 points |
| ☐ | 0 points |
| 6.2.6 Are the methods validated/verified? | Yes | + 5 points |
| ☐ | 0 points |
| 6.2.7 Are special storage conditions maintained for heat-sensitive samples? | Yes | + 5 points |
| ☐ | 0 points |
| 6.2.8 Are all measuring instruments periodically verified/calibrated and laboratory equipment maintained? | Yes | + 5 points |
| ☐ | 0 points |
| 6.2.9 Are laboratory equipment and computerized systems used in the quality control process qualified? | Yes | + 5 points |
| ☐ | 0 points |
| 6.2.10 Does your company have a qualified person? | Yes | + 5 points |
| ☐ | 0 points |
| 6.2.11 Is your company ready to accept a physical (on-site) audit by FSUE SPbSRIVS FMBA of Russia? | Yes | + 5 points |
| ☐ | 0 points |
| 6.2.12 Is your company ready to enter into a Quality Agreement with FSUE SPbSRIVS FMBA of Russia? | Yes | + 5 points |
| ☐ | 0 points |
| **6.3 Clinical trial services**  (please cross out if not applicable) | | |
| 6.3.1 What clinical trial services does your company provide (regulatory affairs, development of protocols, brochures, informed consent forms, screening of trial sites, etc.)? Are any of these services outsourced?  *Please list the services and indicate which ones are outsourced. Are they specified?* | Yes | + 5 points |
| ☐ | 0 points |
| 6.3.2 Are there documents on the procedure for organizing and conducting clinical trials, collecting, registering and providing data in accordance with the protocol and the Rules of Good Clinical Practice? | Yes | + 10 points |
| ☐ | 0 points |
| 6.3.3 Have the terms, storage conditions and access procedures for clinical trial documentation (plans, records, reports) been defined? | Yes | + 5 points |
| ☐ | 0 points |
| 6.3.4 What phases of trials do you conduct? How many trials were conducted over the last 5 years?  *Please indicate the phases of trials and how many trials were conducted over the last 5 years. Are they specified?* | Yes | + 5 points |
| ☐ | 0 points |
| 6.3.5 Do you have a database of trial sites for trials of immunobiological drugs? | Yes | + 5 points |
| ☐ | 0 points |
| 6.3.6 Do the contents of clinical trial monitoring reports comply with the requirements of Good Clinical Practice? | Yes | + 10 points |
| ☐ | 0 points |
| 6.3.7 Is your company ready to accept a physical (on-site) audit by FSUE SPbSRIVS FMBA of Russia? | Yes | + 5 points |
| ☐ | 0 points |
| 6.3.8 Is your company ready to enter into a Quality Agreement with FSUE SPbSRIVS FMBA of Russia? | Yes | + 5 points |
| ☐ | 0 points |
| **6.4 Validation/qualification services**  (please cross out if not applicable) | | |
| 6.4.1 Are there validation/qualification procedures?  *Please attach a list of key procedures* | Yes | + 10 points |
| ☐ | 0 points |
| 6.4.2 Is a risk-based approach used in validation/qualification activities? | Yes | + 5 points |
| ☐ | 0 points |
| 6.4.3 Is the verification/calibration of measuring instruments carried out in a timely manner?  *Please attach a verification/calibration schedule* | Yes | + 10 points |
| ☐ | 0 points |
| 6.4.4 How do you assess the necessity and adequacy of validation testing for a facility?  *Please describe the process or attach the procedure. Are they attached?* | Yes | + 10 points |
| ☐ | 0 points |
| 6.4.5 What tests are carried out during qualification of cleanrooms and inactive premises?  *Please describe the process or attach the procedure. Are they attached?* | Yes | + 5 points |
| ☐ | 0 points |
| 6.4.6 Are computerized systems validated/qualified? | Yes | + 5 points |
| ☐ | 0 points |
| 6.4.7 What system of approval of validation documentation is provided?  *Please describe the process or attach the procedure. Are they attached?* | Yes | + 5 points |
| ☐ | 0 points |
| 6.4.8 Do employees receive specialized training?  *Please attach copies of certificates* | Yes | + 10 points |
| ☐ | 0 points |
| **6.5 Transportation, storage and distribution services**  (please cross out if not applicable) | | |
| 6.5.1 Is qualification carried out for vehicles and/or storage areas?  *Please attach a qualification report* | Yes | + 5 points |
| ☐ | 0 points |
| 6.5.2 Are there regulated procedures describing the process of storage and/or transportation of products? | Yes | + 5 points |
| ☐ | 0 points |
| 6.5.3 Are storage conditions in the warehouse and/or during transportation monitored? | Yes | + 5 points |
| ☐ | 0 points |
| 6.5.4 Are there means of pest control in the warehouse?  *Please attach the trap layout* | Yes | + 5 points |
| ☐ | 0 points |
| 6.5.5 Is there a dedicated quarantine and rejection area? | Yes | + 5 points |
| ☐ | 0 points |
| 6.5.6 Is the equipment for storage and/or transportation of products qualified? | Yes | + 5 points |
| ☐ | 0 points |
| 6.5.7 Have premises and equipment cleaning procedures been developed? | Yes | + 5 points |
| ☐ | 0 points |
| 6.5.8 Is monitoring of the cold chain maintenance during transportation and/or storage of heat-sensitive goods carried out? | Yes | + 5 points |
| ☐ | 0 points |
| 6.5.9 Is there a maintenance program and a verification/calibration program for the equipment used for transportation and storage of goods? | Yes | + 5 points |
| ☐ | 0 points |
| 6.5.10 Is pest control carried out in production facilities?  *Please attach a pest control layout* | Yes | + 5 points |
| ☐ | 0 points |
| **6.6 Inactive premises installation services, inactive premises panel system installation services**  (please cross out if not applicable) | | |
| 6.6.1 Is supplier assessment carried out? Is there a list of approved suppliers?  *Please specify the procedure and attach a list of approved suppliers* | Yes | + 10 points |
| ☐ | 0 points |
| 6.6.2 Is the equipment maintained?  *Please attach a maintenance schedule* | Yes | + 10 points |
| ☐ | 0 points |
| 6.6.3 Does your company provide advanced GMP training for employees?  *Please attach relevant certificates* | Yes | + 10 points |
| ☐ | 0 points |
| 6.6.4 Does your company have experience in providing similar services?  *Please give examples of companies to which you have provided similar services* | Yes | + 10 points |
| ☐ | 0 points |
| 6.6.5 Does your company have an extract from the register of SRO members in the field of construction?  *Please attach the extract* | Yes | + 5 points |
| ☐ | 0 points |
| 6.6.6 Are there procedures that describe the control of changes in methods of analysis, manufacturing processes, equipment or utility systems?  *Please provide evidence of change control activities* | Yes | + 5 points |
| ☐ | 0 points |
| 6.6.7 Are all your company’s processes described in internal procedures?  *Please attach a register of company procedures* | Yes | + 5 points |
| ☐ | 0 points |
| 6.6.8 Can your company provide feedback from other clients/customers?  *Please attach the feedback* | ☐ | 0 points |
| Yes | + 5 points |
| **6.7 Services for preparing clothes and mops for cleaning**  (please cross out if not applicable) | | |
| 6.7.1 What are the requirements for production facilities? What is the classification of premises?  *Please attach a diagram with distribution of cleanliness grades* | Yes | + 5 points |
| ☐ | 0 points |
| 6.7.2 Is the equipment maintained?  *Please attach a maintenance schedule* | Yes | + 5 points |
| ☐ | 0 points |
| 6.7.3 Are inactive premises and equipment qualified?  *Please attach a validation/qualification plan* | Yes | + 5 points |
| ☐ | 0 points |
| 6.7.4 Are production processes validated: washing, drying, sterilization, transportation and storage in the “Sterile” status?  *Please attach a sample validation report* | Yes | + 5 points |
| ☐ | 0 points |
| 6.7.5 Are there approved procedures for the processes (washing, drying, packaging, sterilization, transportation, etc.)?  *Please attach a list of procedures* | Yes | + 5 points |
| ☐ | 0 points |
| 6.7.6 Are records kept of pharmaceutical processes? | Yes | + 5 points |
| ☐ | 0 points |
| 6.7.7 Is the permissible number of washing and sterilization cycles for clothing specified? How is it traced?  *Please describe the process or attach the procedure* | Yes | + 5 points |
| ☐ | 0 points |
| 6.7.8 How is contamination prevented when handling clothes from different customers?  *Please describe the process or attach the procedure. Are they attached?* | Yes | + 5 points |
| ☐ | 0 points |
| 6.7.9 Are clothes intended for use in rooms with different cleanliness grades stored separately?  *Please describe the process or attach the procedure* | Yes | + 5 points |
| ☐ | 0 points |
| 6.7.10 Is pest control carried out in production facilities?  *Please attach a pest control layout* | Yes | + 5 points |
| ☐ | 0 points |
| 6.7.11 Is supplier assessment carried out?  *Please describe the process or attach the procedure* | Yes | + 5 points |
| ☐ | 0 points |
| 6.7.12 Is incoming inspection of raw materials and release control of finished products carried out?  *Please describe the process or attach the procedure* | Yes | + 5 points |
| ☐ | 0 points |
| **6.8 Pharmacovigilance services**  (please cross out if not applicable) | | |
| 6.8.1 Does your company have a Qualified Person Responsible for Pharmacovigilance?  *Please attach the relevant information* | Yes | + 5 points |
| ☐ | 0 points |
| 6.8.2 Do your employees receive advanced training in pharmacovigilance?  *Please attach relevant certificates* | Yes | + 5 points |
| ☐ | 0 points |
| 6.8.3 Are all procedures for pharmacovigilance processes developed?  *Please provide a list of procedures* | Yes | + 5 points |
| ☐ | 0 points |
| 6.8.4 What means and equipment does your company have for carrying out pharmacovigilance?  *Please attach a list Are they attached?* | Yes | + 5 points |
| ☐ | 0 points |
| 6.8.5 Are pharmacovigilance means and equipment validated/qualified?  *Please attach a validation/qualification plan* | Yes | + 5 points |
| ☐ | 0 points |
| 6.8.6 Has your company developed a Business Continuity Plan?  *Please attach the Business Continuity Plan* | Yes | + 5 points |
| ☐ | 0 points |
| 6.8.7 What methods of monitoring the activity and efficiency of the pharmacovigilance system are provided in your company?  *Please describe the process or attach the procedure* | Yes | + 5 points |
| ☐ | 0 points |
| 6.8.8 Is your company ready to enter into a Pharmacovigilance Agreement with FSUE SPbSRIVS FMBA of Russia? | Yes | + 5 points |
| ☐ | 0 points |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **7. The outsourcer’s questionnaire is filled out by:** | | | | | | | | | | | |
| Outsourcer guarantees relevance of information provided in this Questionnaire. | | | | | | | | | | | |
|  |  | |  |  | |  |  | |  |  |  | |
|  | (position) | |  | (Full name) | |  | (signature) | |  | (date) |  | |
| **8. To be filled out by FSUE SPbSRIVS FMBA of Russia** | | | | | | | | | | | |
| Date of receipt of the Questionnaire: | | | | | | | | | | | |
| According to the results of assessment of the Outsourcer’s Questionnaire, the company\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,  providing the services of\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  has the score \_\_\_\_\_\_ points | | | | | | | | | | | |
| Conclusion on the advisability to deal with the Outsourcer:  advisable (above 50 points)  not advisable (0-49 points) | | | | | | | | | | | |
| Notes (need for further audit or status assignment): | | | | | | | | | | | |
| Completed by: | | Position | | | Initials and surname | | | Signature | | Date | |
|  | | |  | | |  | |  | |
| Agreed by: | |  | | |  | | |  | |  | |
| Approved by | |  | | |  | | |  | |  | |