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| MANUFACTURER’S QUESTIONNAIRE |
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| **Please give objective answers to the following questions, as your answers will be used for preliminary assessment (please fill in the unshaded cells).** |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. Key information on the company/legal entity** | | | | | | | | |
| Full name | |  | | | | | | |
| Actual address | |  | | | | | | |
| Telephone/fax | |  | | | | | | |
| Website of the company/legal entity: | |  | | | | | | |
| The website contains information on the range of products, licenses, quality certificates and product safety | |  | | | | | | |
| Year of incorporation of the company/legal entity  Date of entry in the Unified State Register of Legal Entities (EGRUL)/Principal State Registration Number of the Individual Entrepreneur (OGRNIP) | |  | | | | | | |
| 1. **2. Please provide the contact information on the company/legal entity:** | | | | | | | | |
| **2.1 Full name of the head of the company/legal entity** | | | | | | | | |
| **2.2 Full name and position of the nominated contact person** | | | | | | | | |
| Telephone  Fax | | | | | | | | |
| E-Mail | | | | | | | | |
| **3. Personnel information** | | | | | | | | |
| Total personnel | | |  | | | | | |
| Quality Unit personnel | | |  | | | | | |
| Production personnel | | |  | | | | | |
| Copy of the organizational structure (if available) | | | Attached | | | Not attached | | |
| **4. Types of manufactured products** | | | | | | | | |
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| **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 | | + 4 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 | | n/a |
| ☐ | | n/a |
| 5.4 Does your company carry out customer satisfaction assessments?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 5.5 Has your company/legal entity been inspected by any regulatory authority or another pharmaceutical company/legal entity in the last 2 years?  *Please specify the company/legal entity* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| **6. Quality system** | | | | | | | | |
| 6.1 Do you have a quality policy and quality manual?  *Please specify the procedure* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 6.2 Has any procedure or local regulation been drafted for management of documents and records?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 6.3 Has a training program been developed for personnel involved in the pharmaceutical process and quality control?  *Please attach the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 6.4 Has a procedure or local regulation been developed for handling product quality claims?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 6.5 Are internal audits conducted and have CAPAs been developed?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 6.6 Is a supplier/outsourcer assessment carried out?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 6.7 Are discrepancies monitored and CAPA developed?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 6.8 Has a product recall procedure been drafted?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 6.10 Is change control carried out?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| **7. Production and storage** | | | | | | | | |
| 7.1 Have procedures for changing clothes by personnel been developed?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 5 points |
| ☐ | | 0 points |
| 7.2 Have equipment cleaning procedures been developed?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 7.3 Have production procedures been developed? Are all critical operations documented?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 7.4 Has a maintenance program been developed for equipment and utility systems?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 7.5 Has an equipment verification/calibration/qualification program been developed?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 7.6 Are the production environment and storage conditions in the warehouse monitored?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| 7.7 Are there means of pest control in the warehouse?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| **8. Quality Control** | | | | | | | | |
| 8.1 Are discrepancies from specifications/regulatory documents governed?  *Please specify the procedure or describe the process* | | | | | | Yes | | + 5 points |
| ☐ | | 0 points |
| **9. Related quality documents** | | | | | | | | |
| 9.1 Please attach related quality documents for the supplied goods (e.g. declaration of conformity of goods, declaration of conformity with TR CU, certificates of conformity of goods, quality certificate, etc.)  *Are they attached?* | | | | | | Yes | | + 4 points |
| ☐ | | 0 points |
| **10. Will the company/legal entity give consent to an audit by FSUE SPbSRIVS FMBA of Russia?** | | | | | | Yes | | + 5 points |
| ☐ | | 0 points |
| **11. The Manufacturer’s Questionnaire is filled out by:** | | | | | | | | |
| The company/legal entity guarantees that the information provided in this Questionnaire is true | | | | | | | | |
| |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  | | (position) |  | (Full name) |  | (signature) |  | (date) | | | | | | | | | |
| **12. To be filled out by FSUE SPbSRIVS FMBA of Russia** | | | | | | | | |
| Date of receipt of the Questionnaire: | | | | | | | | |
| According to the results of assessment of the Manufacturer’s Questionnaire,  company\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,  that supplies\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  has the score \_\_\_\_\_\_ points | | | | | | | | |
| Conclusion on the advisability to deal with the manufacturer:  advisable (above 60 points)  not advisable (0-59 points) | | | | | | | | |
| Notes (need for further audit or status assignment): | | | | | | | | |
| **Completed by:** | Position | | | Initials and surname | Signature | | Date | |
|  | | |  |  | |  | |
| **Agreed by:** |  | | |  |  | |  | |
| **Approved by** |  | | |  |  | |  | |