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| **CONTRACT**  *for Conducting Good Manufacturing Practice Compliance Inspection* | | | | |
| Yerevan | | --/--/---- | | |
| “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”\_\_\_\_\_\_\_\_\_\_represented by Director General \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (hereinafter referred to as “the Applicant”), on one hand,  and,  “Center of Drug and Medical Technology Expertise” SNCO represented by Director Arayik Baghryan (hereinafter referred to as “the Agency”), on the other hand, both hereinafter referred to as “the Parties”, have entered into this Contract (hereinafter referred to as “the Contract”) as follows: | | | | |
| 1. **SUBJECT MATTER OF THE CONTRACT** | | | | |
| The Agency undertakes to conduct a Good Manufacturing Practice Compliance inspection (hereinafter “the Inspection”) according to the EAEU GMP rules and the Applicant undertakes to reimburse inspection costs in the manner prescribed by the Contract. | | | | |
| * 1. The Inspection is performed according to the legislation of the Republic of Armenia. | | | | |
| * 1. The name and address of the each site subject to Inspection as well as the type of product/process and Inspection term are mentioned in the Appendixes to the Contract (hereinafter “Appendix”) forming the integral part of the Contract. | | | | |
| * 1. The definitions related to the Inspections are interpreted according to the meanings provided by the legislation of the Republic of Armenia. | | | | |
| 1. **RIGHTS AND OBLIGATIONS OF THE PARTIES** | | | | |
| * 1. **The Agency shall be obliged to:** | | | | |
| * + 1. perform the undertaken responsibilities in a timely manner and in accordance with the Contract, based on the legislation of the Republic of Armenia; | | | | |
| * + 1. do not to involve any third party in the Inspection process without any other additional written agreement between the Parties; | | | | |
| * + 1. immediately notify in the written form to the Applicant in case any obstacle has been identified, which can significantly impact the results of the Inspection or which can generate any other negative outcomes for the Applicant. | | | | |
| * 1. **The Agency has the right to:** | | | | |
| * + 1. demand from the Applicant to make payments related to the Inspection in the manner specified in the 3th Part of this Contract; | | | | |
| * + 1. require the documents and data necessary for conducting the Inspection; | | | | |
| * + 1. suspend the Inspection process in case of not fulfillment by the Applicant of the obligations in relation to the Inspection under the legislation of the Republic of Armenia or the Contract; | | | | |
| * + 1. perform any other operations under the legislation of the Republic of Armenia and necessary for properly conducting the Inspection. | | | | |
| * 1. **The Applicant shall be obliged to:** | | | | |
| * + 1. make payments in the manner specified in the 3th Part of this Contract; | | | | |
| * + 1. in case of changes in Inspection terms on its own initiative, reimburse the actual costs associated with such changes; | | | | |
| * + 1. ensure the implementation of the necessary actions for the Inspection defined by the legislation of the Republic of Armenia. | | | | |
| * 1. **The Applicant shall have the right to:** | | | | |
| * + 1. demand to conduct the Inspection in accordance with the procedure established by the legislation of the Republic of Armenia; | | | | |
| * + 1. in case of identifying deviations or other inconsistencies from the Contract, immediately notify the Agency. | | | | |
| 1. **CONTRACT PRICE, PAYMENT FORM AND TERMS** | | | | |
| * 1. The Inspection fee is defined in the Appendix. | | | | |
| * 1. The Inspection process shall start only with the document confirming the receipt of 100% prepayment of the Inspection fee defined in the Appendix. | | | | |
| * 1. The Applicant shall additionally be obliged to reimburse the expenses actually incurred by the Agency in connection with the implementation of the Inspection, if any, within 5 working days after the submission of the billing documents provided by the Agency. | | | | |
| * 1. Payments under by the Contract shall be made to the bank account specified in the Contract by the Agency. | | | | |
| 1. **HANDOVER AND ACCEPTANCE OF THE INSPECTION RESULTS** | | | | |
| * 1. By the end Inspection report shall be provided to the Applicant according to the legislation once the document confirming the receipt of the amount on the relevant bank account of the Agency and Agency shall issue the Invoice. | | | | |
| * 1. In case of submission of written objections by the Applicant and not reaching an agreement in that respect, the dispute shall be resolved by manner prescribed by the Contract and legislation of the Republic of Armenia. | | | | |
| 1. **TERM AND TERMINATION OF THE CONTRACT** | | | | |
| * 1. This Contract is signed for an indefinite period. This Contract and the Appendix are effective from the date of signature of both Parties and remain in force till the complete and proper fulfillment of the obligations thereunder. | | | | |
| * 1. The Contract may be terminated by mutual agreement of the Parties, as well as in accordance with the legislation of the Republic of Armenia. | | | | |
| * 1. The Applicant is entitled to early unilateral termination of the Contract with the full reimbursement to the Agency of the Inspection costs. The Inspection cost shall not be refunded. In case of inconsistencies with this respect between the terms defined by the Appendix and by this Contract, the terms of the Appendix shall apply. | | | | |
| * 1. The Agency is entitled to early unilateral termination of the Contract if the Applicant does not transfer the prepayment within one month from the Inspection date defined in the Appendix. | | | | |
| * 1. In case of non-payment or improper payment by the Applicant within the manner and timeframe under the Contract, the Agency is entitled to unilateral termination of the Contract without prior notice and to reimbursement by the Applicant of the actual costs incurred, as well as has the right not to return the payments already made by the Applicant. | | | | |
| 1. **LIABILITY OF THE PARTIES** | | | | |
| * 1. The Agency shall be liable for improper implementation of the Inspection. | | | | |
| * 1. The Agency shall not be liable for any defects in the Inspection result which did not arise through the fault of the Agency, including the defects arisen due to the fault of the Applicant or non-fulfillment of the obligations under the Contract. | | | | |
| * 1. The Agency does not provide any other guarantees other than the diligent and quality fulfillment of the obligations under the Contract; in particular, it does not guarantee the result of the Inspection, regardless of the predictability of the result. | | | | |
| * 1. The Parties shall be liable for non-fulfillment or improper fulfillment of the obligations under the Contract in accordance with the legislation of the Republic of Armenia. | | | | |
| 1. **CONFIDENTIALITY** | | | | |
| * 1. The Agency undertakes to maintain the confidentiality of its activities, not to publish professional, business or other information about the Applicant, as well as not to use this information for its personal benefit or for the benefit of third parties. | | | | |
| * 1. The Agency shall not take out from the site of the Applicant any documents and storage devices without the consent of the Applicant. | | | | |
| * 1. The Agency ensures that it has relevant non-disclosure agreements regarding the Applicant and information related thereto with its employees who are going to conduct the Inspection under the Contract. | | | | |
| 1. **FORCE MAJEURE** | | | | |
| * 1. Failure to comply fully or in part with the obligations under the Contract shall be waived by the Parties if it was the result of a force majeure that arose after the conclusion of the Contract which the Parties could not have foreseen or prevented. Such situations include natural disasters, war, acts of state bodies, changes in legislation, etc., which arise against the will of the Parties, making it impossible to fulfill the obligations under the Contract. | | | | |
| * 1. If the force majeure continues for more than three months, each Party shall have the right to terminate the Contract by notifying the other Party in advance. The termination of the Contract on such a basis shall not release the Applicant from the reimbursement of the costs actually incurred. | | | | |
| 1. **COMMUNICATION OF THE PARTIES** | | | | |
| * 1. Communication (correspondence) between the Parties within the framework of the implementation of the Contract, including the provision of information to the Agency by the Applicant, shall be carried out in writing (by hand or per post), as well as by means of electronic communication. In case of correspondence by e-mail, the notification shall be deemed received on the day following its sending. | | | | |
| * 1. Communication (correspondence) between the Parties within the framework of the implementation of the Contract shall be carried out at the addresses specified in the Contract. In case of change of the addresses, the Parties shall provide the new address. In case of breach of the obligation set in this clause, the notifications made under the Contract shall be sent to the last known postal address and deemed delivered, regardless of whether it has been received by the addressee. | | | | |
| * 1. The Applicant states that it is aware and gives its consent to the Agency (including its staff) to record all telephone conversations during the operation of the Contract. | | | | |
| 1. **FINAL PROVISIONS** | | | | |
| * 1. This Contract shall be governed by the legislation of the Republic of Armenia. | | | | |
| * 1. In case the disputes arising out of the implementation and termination of the Contract are not settled through negotiations, they shall be resolved before the courts of the Republic of Armenia. | | | | |
| * 1. The invalidity of any provision of the Contract shall not affect the validity of any other provision of the Contract, if it could have been executed without the incorporation of the invalid part. | | | | |
| * 1. Any amendments and supplements to this Contract shall be made by drawing up a single document signed by the Parties. | | | | |
| * 1. The contract is made in two equal copies in English. One copy of the Contract is given to each Party. | | | | |
| * 1. This Contract, its Appendixes and amendments may be signed by exchanging documents by means of electronic communication. | | | | |
| **11. REQUISITES AND SIGNATURES OF THE PARTIES** | | | | |
| THE APPLICANT | | | THE AGENCY | |
| “----------” ---------- | | | “Center of Drug and Medical Technology Expertise” SNCO | |
| Address |  | | Address | 49/5 Komitas ave, Yerevan 0051, Republic of Armenia |
|  |  | | TIN | 08275442 |
| e-mail |  | | e-mail | info@ampra.am |
| Bank requisites |  | | Account No | 900018009804  Operations Department |
|  |  | |
| Director ---------------------------- | | | Director Arayik Baghryan | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_seal (if available) | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ seal (if available) | |