

## **QUALITY**

- 5.1.0 If applicable and so required, a mutually agreeable quality agreement (**the “Technical Agreement”**) in accordance with Customer’s and Service Provider’s standard operating procedures and in conformity with any regulatory authority requirements and applicable law (including cGMPs). In the event that a formal Technical Agreement is not required or until a Technical Agreement is entered into between the parties, this Agreement in conjunction with all applicable regulatory requirements, and applicable law (including cGMPs) shall govern the parties’ responsibilities with respect to procedures impacting the Services. To the extent that any inconsistencies or conflicts exist between the Technical Agreement and this Agreement, the provisions in the Technical Agreement shall prevail with respect to quality matters. As set forth in clause 13, Customer may immediately terminate this Agreement upon written notice to the Service Provider in the event that the Technical Agreement is terminated in accordance with the respective terms of either document provided.
- 5.1.1 Provider management confirms that they use adequate equipment and have the required knowledge and experience, and competent personnel to carry out satisfactorily the work ordered by Customer under this Agreement.
- 5.1.2 The Customer is responsible for providing Provider personnel with training on Customer processes and procedures.
- 5.1.3 The Provider is responsible for maintaining their own equipment in terms of operational status and condition.
- 5.1.4 The Provider will provide all documentation relevant to the work carried out to the Customer, prior to leaving site.
- 5.1.5 The Customer will fulfil duties under Good Manufacturing Practice (GMP) and will review the documentation produced by the Provider to ensure compliance with site procedures and GMP. Performance reviews will also be conducted periodically by the Customer.



- 5.1.6 The Provider shall permit reasonable access, at agreed pre-determined times, to permit audits of the relevant facilities by the Customer or the Competent Authorities.
- 5.1.7 The Provider has a responsibility to resolve promptly, to the mutual satisfaction of both parties, any agreed deficiencies highlighted during review of service/documents or during an audit.
- 5.1.8 The Provider may only carry out work in line with the relevant prescribed procedures and Provider work instruction.
- 5.1.9 The Provider shall not make any unauthorised changes to the Customer's facility or equipment without prior written approval from the Customer.
- 5.1.10 The Provider shall not subcontract any work ordered by Customer under this Agreement to another party without prior written approval from Customer.
- 5.1.11 The Provider and Customer designate as persons for all quality and technical matters the persons named on Schedule 2.

#### **5.2.0 GMP**

- 5.2.1 Service Provider management confirms that they use adequate equipment and have the required knowledge and experience, and competent personnel to carry out satisfactorily the work ordered by Customer under this Agreement.
- 5.2.2 The Customer is responsible for providing Service Provider personnel with training on Customer processes and procedures.
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