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| | | | | Proprietary & Confidential Information |
| VENDOR MANAGEMENT | | | | |

- 6.2 When product ownership changes, (e.g., through acquisitions) [Company Name] management must consider the complexity of the change and ensure the Quality Agreements and other contracts are updated and the necessary information is appropriately transferred.
- 6.3 Documents and records regarding vendor activities are maintained according to [Company Name] document retention procedures and minimally for three (3) years after the contract are terminated.

7.0 PROCEDURE

7.1 Vendor Qualification

- 7.1.1 The GXP operational department follows [Company Name] PH50, Vendor Qualification procedures for qualifying a vendor for a GXP product or service and performs a risk assessment to categorize the vendor as high risk, moderate risk, or low risk.
- 7.1.2 The qualification documentation is stored in the vendor file as described below.

7.2 Vendor Management

- 7.2.1 Once the vendor is qualified and listed on the Approved Vendor List, the responsible GXP operational department ensures that the vendors are properly managed throughout the terms of the agreement.
- 7.2.2 Effective management of vendors minimally includes:
- 7.2.2.1 Regularly scheduled meetings or teleconferences with the vendor to discuss the details of scheduling, delivery, issues as they arise.
 - 7.2.2.2 Periodic visits by the GXP operational department to the vendor's site to monitor performance of activities, as required by the nature and criticality of the vendor's service provided.
 - 7.2.2.3 Tracking regulatory compliance history.
 - 7.2.2.4 Resolving quality problems as they arise.
 - 7.2.2.5 Implementing corrective and preventive actions as needed.
 - 7.2.2.6 Reporting performance metrics to Quality Assurance and Executive Management.
- 7.2.3 Quality Assurance ensures that vendors are qualified to remain on the Approved Vendor List by performing periodic quality audits according to [Company Name] audit procedures. The frequency of audits depends on the nature of the product or service provided. The following criteria may be used as a guideline in determining the frequency of audits:
- 7.2.3.1 High risk vendors should be audited between 12 and 18 months, unless otherwise justified. If a more frequent audit is required, document the rationale in the vendor qualification documents.

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