**{{ SupplierEvaluation }}**

**General Information**

|  |  |
| --- | --- |
| Company name : | Click here to enter text. |
| Company address (legal entity): | Street:           Klicken Sie hier, um Text einzugeben.  Postal Code: Klicken Sie hier, um Text einzugeben.  PO-Box:         Klicken Sie hier, um Text einzugeben.  City/Country:      Klicken Sie hier, um Text einzugeben. |
| Company address (facility) [if deviating from legal address]: | Street:           Klicken Sie hier, um Text einzugeben.  Postal Code: Klicken Sie hier, um Text einzugeben.  PO-Box: Klicken Sie hier, um Text einzugeben.  City/Country :     Klicken Sie hier, um Text einzugeben. |
| Competence profile of the company:    Klicken Sie hier, um Text einzugeben. | |
| Contact person: | Name: Klicken Sie hier, um Text einzugeben.  Function: Klicken Sie hier, um Text einzugeben.  Phone: Klicken Sie hier, um Text einzugeben.  E-mail: Klicken Sie hier, um Text einzugeben. |
| Goods/service category:    Klicken Sie hier, um Text einzugeben. | |

**Type of Supplier/Customer Evaluation**

|  |  |  |
| --- | --- | --- |
| This Evaluation is done for | **☐** new Supplier/Customer  (Initial evaluation) | **☐** existing Supplier/Customer (reevaluation) |

|  |  |
| --- | --- |
| Only for existing Supplier | |
| Date of last reevaluation | DD.MM.YYYY |
| Current Risk Class (1, 2,3) |  |
| Current RPN (1-27 points) |  |

**Scope of Supplier/Customer Evaluation**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **YES** | **NO** | **N/A** |
| Non-Disclosure Agreement (NDA) |  |  |  |
| List of Supplier’s Clients |  |  |  |
| List of Supplier’s products/services |  |  |  |
| Supplier Self-Assessment Form |  |  |  |
| Annexures to Supplier Self-Assessment Form (copies of Supplier’s internal docs) |  |  |  |
| Relevant Authorizations (MIA, WDA) |  |  |  |
| Relevant Certificates (e.g., GMP, GDP, GLP, GDP, ISO, EDQM) |  |  |  |
| Supplier’s CoAs |  |  |  |
| Technical visit conclusion/statement |  |  |  |
| Audit report |  |  |  |
| CAPA responds and evidences |  |  |  |
| Non-conformances/deviation reports, related to materials/services (for approved Supplier) |  |  |  |
| Previous {{ SupplierEvaluation }} records |  |  |  |
| Other: Click here to enter text. |  |  |  |
| Comment: Click here to enter text. | | | |

**Risk Priority Number (RPN) Calculation**

|  |  |  |  |
| --- | --- | --- | --- |
| **Ranking** | **Severity (S)** | **Probability (P)** | **Detection (D)** |
| 1 | Negligible effect on final products or operations. | Potential failure or defect with Supplier’s related operations never happened before (quality historical data, regulatory agencies alerts, market benchmark data). | Established appropriate testing / assessment system which allows detecting Supplier’s product/service defects in 100% cases.  Well-defined critical quality attributes and critical operational parameters. |
| 2 | A reasonable expectation that a malfunction or defect could potentially result in minor operational issues or other minor quality problems. | Several minor incidents since the previous evaluation that did not result in significant defects or issues. | Established appropriate testing / assessment system which allows to detect of Supplier’s material/service defects with a low probability of detecting errors.  Appropriate materials specifications, test methods, sampling plan are in place.  Not all critical quality attributes and critical process parameters are defined and established. |
| 3 | Reasonable expectation that faults or defect will case the significant operational quality issue. | Occurs frequently  >1% batches, lots, events. | Impossible to detect before failure or issue with product, process, quality will happen. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| RPN=(S)X(P)X(D) | (S) | (P) | (D) | Overall RPN |
|  |  |  |  |

**Risk Class determination**

|  |  |  |
| --- | --- | --- |
| **Risk Class** | **RPN range** |  |
| 1 | 9-27 |  |
| 2 | 4-8 |  |
| 3 | 1-3 |  |

**Supplier/Customer Evaluation Conclusion**

|  |  |  |  |
| --- | --- | --- | --- |
| **Conclusion** | | **Related decisions and commitments** | |
| **Supplier/Customer is qualified** |  | **Improvements, risk reduction, CAPA measurements are required before qualification/ requalification** |  |
| **Supplier/Customer isn’t qualified** |  | **Improvements, risk reduction, CAPA measurements are required and can be implemented after qualification/requalification** |  |
| **Supplier/Customer is requalified** |  |
| **Supplier/Customer is disqualified** |  | **Improvements, risk reduction, CAPA measurements are not required** |  |

**Next planned Supplier/Customer requalification due date\_\_\_\_\_\_\_\_\_\_\_\_\_\_** DD.MM.YYYY

**Improvement and CAPA measures are defined as part of supplier/customer qualification/requalification**

|  |  |  |
| --- | --- | --- |
| **CAPA number** | **CAPA measure description** | **Planned due date** |
|  |  |  |

**Document approval**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Name** | **Date** | **Signature** |
| **Author’s designation** |  |  |  |
| **Reviewer’s designation** |  |  |  |
| **Approver’s designation**  **{{ QualityOrganizationHead }}** |  |  |  |