**<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 Evaluation**

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

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

**Scope of Supplier 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 Certificates (e.g., GMP, GLP, GDP, ISO, EDQM)  |[ ] [ ] [ ]
| Samples testing results  |[ ] [ ] [ ]
| Supplier’s CoAs  |[ ] [ ] [ ]
| Technical visit conclusion/statement  |[ ] [ ] [ ]
| Audit report  |[ ] [ ] [ ]
| CAPA respond and evidences  |[ ] [ ] [ ]
| Non-conformances/deviation reports, related to materials/services (for approved Supplier)  |[ ] [ ] [ ]
| Trend analysis/Product Quality Reviews for related materials  |[ ] [ ] [ ]
| 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 processes. | Potential failure or defect with Supplier’s related materials/services never happened before (quality historical data, regulatory agencies alerts, market benchmark data). | Established appropriate testing / assessment system which allows to detect Supplier’s material/service defects in 100% cases.Appropriate materials specifications, test methods, sampling plan are in place.Well defined critical quality attributes and critical process parameters. |
| 2  | A reasonable expectation that a malfunction or defect could potentially result in minor product defects 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 Supplier’s material/service defects with 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 product defects, process defects, or significant 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 Evaluation Conclusion**

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

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

**Improvement and CAPA measures defined as part of supplier 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>** |  |  |  |