**<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>** |  |  |  |