|  |
| --- |
| **SECTION 1 – COMPANY OVERVIEW** |
| **Business Entity & Nature of Business** |  |
| **Industries Served** |  |
| **No. of Years in Business** |  |
| **Total No of Employees** |  |

|  |
| --- |
| **SECTION 2 – QUALITY SYSTEM** |
| **No.** | **Question** | **Yes** | **No** | **Comments** |
| **1** | Is there a quality management system implemented? Is it covered by any ISO certification? |  |  |  |
| **2** | Is there a quality manual and written procedures (policies/SOPs) describing all GDP related processes? |  |  |  |
| **3** | Are the written procedures (policies/SOPs) based on current GDP principles and local law (where applicable)? |  |  |  |
| **4** | Have all subcontractors, vendors, customers, and suppliers been qualified? Are they regularly reviewed/re-qualified? Are audits performed on 3rd party/sub-contractors? |  |  |  |
| **5** | Is there a deviation procedure in place? |  |  |  |

|  |
| --- |
| **SECTION 3 – ORGANISATION & PERSONNEL** |
| **No.** | **Question** | **Yes** | **No** | **Comments** |
| **1** | Is there an up-to-date organogram of the company to show roles and responsibilities and reporting lines |  |  |  |
| **2** | Is there a dedicated Qualified/Responsible Person (with adequate experience and qualification) appointed? |  |  |  |
| **3** | Are employees trained in GDP principles? |  |  |  |
| **4** | Do all personnel have job descriptions and are they updated regularly? |  |  |  |
| **5** | Are training and qualification records kept? |  |  |  |
| **6** | Are contractors/3d parties, that perform any function on behalf of the company, provided with training relevant to their function? |  |  |  |

|  |
| --- |
| **SECTION 4 – EQUIPMENT** |
| **No.** | **Question** | **Yes** | **No** | **Comments** |
| **1** | Is there a documented approach for the implementation and modification of equipment including operation and maintenance of equipment? |  |  |  |
| **2** | Is there a maintenance/service schedule? |  |  |  |
| **3** | Are maintenance records available? |  |  |  |
| **4** | Are there procedures in place to deal with temperature excursions (alarms, notifications)? |  |  |  |

|  |
| --- |
| **SECTION 5 – COMPLAINTS, RETURNS, SUSPECTED FALSIFIED MEDICINES AND MEDICINAL PRODUCT RECALL** |
| **No.** | **Question** | **Yes** | **No** | **Comments** |
| **1** | Are there procedures in place to manage complaints? |  |  |  |
| **2** | Are complaints recorded and investigated to identify the origin and reason? |  |  |  |

|  |
| --- |
| **SECTION 6 – OUTSOURCED ACTIVITIES** |
| **No.** | **Question** | **Yes** | **No** | **Comments** |
| **1** | Are there contracts in place defining responsibilities for each party? |  |  |  |
| **2** | An audit of the Contract Acceptor is performed before the beginning of the outsourced activities |  |  |  |
| **3** | After the beginning of the outsourced activities audits are performed periodically |  |  |  |

|  |
| --- |
| **SECTION 7 – SELF INSPECTIONS** |
| **No.** | **Question** | **Yes** | **No** | **Comments** |
| **1** | A self-­ inspection programme is implemented to cover all aspects of GDP and compliance within a defined time frame |  |  |  |
| **SECTION 8 – TRANSPORTATION** |
| **No.** | **Question** | **Yes** | **No** | **Comments** |
| **1** | Required storage conditions are maintained during transportation |  |  |  |
| **2** | Vehicles and equipment are suitable and appropriately equipped to prevent exposure of the products to conditions that could affect their quality and packaging integrity, and to prevent contamination of any kind |  |  |  |
| **3** | Procedures are in place for the operation and maintenance of all vehicles and equipment, including cleaning and safety precautions |  |  |  |
| **4** | Delivery drivers (including contract drivers) are trained in the relevant areas of GDP |  |  |  |
| **5** | Deliveries are made directly to the address stated on the delivery note |  |  |  |
| **6** | Do you use 3rd party contractors to transport product? (outsourced) |  |  |  |
| **7** | Is there a procedure for the operation and maintenance of vehicles |  |  |  |
| **8** | Have the delivery routes been risk assessed to determine where temp controls are required? |  |  |  |
| **9** | Is the equipment used for temp monitoring maintained and calibrated? How? |  |  |  |
| **10** | Are there dedicated vehicles used? |  |  |  |
| **11** | Has temp mapping been carried out on vehicles, taken into account seasonal variations? |  |  |  |
| **12** | Is the integrity of goods checked before unloading at the destination? |  |  |  |
| **13** | Is there an inspection made of the transport equipment cleanliness before loading? |  |  |  |

**Completed by:**

**Job Title:**

|  |
| --- |
| **THE FOLLOWING SECTIONS ARE TO BE COMPLETED POST AUDIT BY ASC PERSONNEL** |
| **SECTION 9 – CONCLUSION AND ADDITIONAL NOTES** |
|  |

Approved by:

|  |  |
| --- | --- |
| Signature: |  |
| Job Title: |  |
| Date: |  |