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| **SECTION 1 – COMPANY OVERVIEW** | |
| **Business Entity & Nature of Business** |  |
| **Industries Served** |  |
| **No. of Years in Business** |  |
| **Size of Facility** |  |
| **Total No. of Employees** |  |
| **List of Departments** |  |
| **No. of Employees in Each Department** |  |
| **Operating Hours** |  |
| **Operating Shifts** |  |
| **Contact Details** |  |
|  | |
| **SECTION 2 – Quality System** | |

| **No.** | **Question** | | **Yes** | **No** | | **Comments** | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Is there a quality management system implemented? Under what industry standard/regulation is QMS designed? | |  |  | |  | | |
|  | Is there a quality manual and written procedures (policies/SOPs) describing all GDP related processes? | |  |  | |  | | |
|  | Is there a document control system in place ensuring proper design, approval, review, and distribution of necessary documentation? | |  |  | |  | | |
|  | Are the written procedures/policies based on current GDP principles and industry/regulatory/contractual requirements? | |  |  | |  | | |
|  | Is there a written procedure and system in place for archiving and document retention? | |  |  | |  | | |
|  | Is there a procedure for internal audits? Is there an audit plan to cover all areas of concern? | |  |  | |  | | |
|  | Does a formal management review of the Quality Management System exist and how often is it held?  Does the review cover all the elements of the QMS and are all action plans as a result of that meeting tracked to completion? | |  |  | |  | | |
|  | Have all subcontractors, vendors, customers, and suppliers been qualified?  Are they regularly reviewed/re-qualified?  Are audits performed on 3d party/sub-contractors? | |  |  | |  | | |
|  | Are there contracts/agreements in place for all customers, vendors, suppliers?  Are these agreements maintained to ensure validity (lifecycle)? | |  |  | |  | | |
|  | Is there a change control system in place? | |  |  | |  | | |
|  | Is there a deviation procedure in place? | |  |  | |  | | |
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| **Section 3 – Organisation and Personnel** | | | | | | | | |
|  | Is there an up-to-date organogram of the company to show roles and responsibilities and reporting lines | |  |  | |  | | |
|  | Is there a dedicated Qualified/Responsible Person (with adequate experience and qualification) appointed? | |  |  | |  | | |
|  | Is there a training programme for new employees and refresher/ongoing training for established employees? | |  |  | |  | | |
|  | Are employees trained in GDP principles? | |  |  | |  | | |
|  | Do all personnel have job descriptions and are they updated regularly? | |  |  | |  | | |
|  | Are contractors/3d parties, that perform any function on behalf of the company, provided with training relevant to their function? | |  |  | |  | | |
|  | | | | | | | | |
| **SECTION 4 – Premises** | | | | | | | | |
|  | For premises which are not directly operated by the wholesale distributor, is there a contract in place?  Is this verified if the premises are covered by a wholesale distribution authorisation? | |  |  | |  | | |
|  | Are areas controlled to prevent unauthorised access? | |  |  | |  | | |
|  | Are receiving and dispatch bays protected from prevailing weather conditions e.g., roller shutter door, curtains | |  |  | |  | | |
|  | Does the warehouse contain areas design to store the following? How is access and inventory of those areas controlled? | |  |  | |  | | |
|  | * product suspected of falsification | |  |  | |  | | |
|  | * Returned product | |  |  | |  | | |
|  | * Rejected product | |  |  | |  | | |
|  | * Product awaiting disposal | |  |  | |  | | |
|  | * recalled product and medicinal products not intended for the EU market | |  |  | |  | | |
|  | Is there adequate separation between the receipt and dispatch areas and storage areas? | |  |  | |  | | |
|  | Are procedures relating to personnel hygiene like health, hygiene and clothing established and observed? | |  |  | |  | | |
|  | Are there cleaning instructions and records in place? | |  |  | |  | | |
|  | Are facilities designed and equipped to afford protection against the entry of insects, rodents, or other animals? | |  |  | |  | | |
|  | Is there a preventive pest control programme in place? | |  |  | |  | | |
|  | Are suitable equipment and procedures in place to ensure adequate control of the environment? | |  |  | |  | | |
|  | Is the storage areas temperature mapped? | |  |  | |  | | |
|  | Is the Equipment used to control or to monitor the environment, calibrated and is their correct operation and suitability verified at defined intervals by the appropriate methodology? | |  |  | |  | | |
|  | Is there an appropriate alarm system in place to provide alerts when there are deviations from pre­ defined storage conditions? | |  |  | |  | | |
|  | | | | | | | | |
| **SECTION 5 – Equipment** | | | | | | | | |
|  | Is there a documented approach for the implementation and modification of equipment including relocation, operation and maintenance of equipment? | |  |  | |  | | |
|  | Has the site implemented a calibration schedule?  Is there evidence (records) of regular (quality-critical) equipment calibration? | |  |  | |  | | |
|  | Is there a Preventative Maintenance Plan? | |  |  | |  | | |
|  | Is their ancillary equipment in place to accommodate power outage or failure of cooling/heating units? | |  |  | |  | | |
|  | Are there procedures in place to deal with temperature excursions (alarms, notifications)? | |  |  | |  | | |
|  | Do computerized systems have the appropriate access levels to protect from unauthorized changes? | |  |  | |  | | |
|  | Is data is secured by physical or electronic means against wilful or accidental damage | |  |  | |  | | |
|  | | | | | | | | |
| **SECTION 6 – Documentation** | | | | | | | | |
|  | Who is responsible for and approving the SOPs? | |  |  | |  | | |
|  | How long are the documents retained for? | |  |  | |  | | |
|  | How is version control managed? | |  |  | |  | | |
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| **SECTION 7 – Qualification of Supplier** | | | | | | | | |
| 46 | Are all supplies of medicinal products obtained only from persons/organisations who are in possession of a wholesale distribution authorisation, or who are in possession of a manufacturing authorisation which covers the product in question? | |  |  | |  | | |
| 47 | When medicinal product is obtained from another wholesale distributor: how is compliance with the principles and guidelines of good distribution practices of the supplying wholesale distributor verified? | |  |  | |  | | |
| 48 | When medicinal product is obtained from manufacturer or importer how is it verified that the manufacturer or importer holds a manufacturing authorisation? | |  |  | |  | | |
| 49 | Is the purchase of medicinal products is controlled by written procedures? | |  |  | |  | | |
| 50 | Is there appropriate qualification performed prior to any procurement? | |  |  | |  | | |
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| **SECTION 9 – Qualification of Customer** | | | | | | | | |
| 51 | How is it ensured that medicinal products are only supplied to persons/organisations who are themselves in possession of a distribution authorisation or who are authorized or entitled to supply medicinal products to the public | |  |  | |  | | |
| 52 | How are customers qualified?  Does the qualification of customers periodic re­checks include?  o requesting evidence of qualifications or entitlement according to national legislation.  o verifying status on an authority website  o requesting copies of customer's authorisations | |  |  | |  | | |
| 53 | Is the qualification of customers being appropriately documented? | |  |  | |  | | |
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| **SECTION 10 Receipt of Goods** | | | | | | | | |
| 54 | How does the site ensure that?   * the arriving consignment is correct * the medicinal products originate from approved suppliers * the medicinal products have not been damaged or altered during transportation | |  |  | |  | | |
| 55 | For medicinal products which require special storage or security measures, how does the site ensure that these products are transferred to appropriate storage facilities immediately after appropriate checks have been conducted? | |  |  | |  | | |
| 56 | Does the site have procedures in place which define that in the event of any suspicion of falsified medicinal product, the batch is immediately segregated? | |  |  | |  | | |
| 57 | How does the site ensure that in the event of any suspicion of falsified medicinal product, the batch is immediately reported to the national competent authority? | |  |  | |  | | |
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| **SECTION 11 – Storage** | | | | | | | | |
| 58 | Are medicinal products stored separately from other products? | |  |  | |  | | |
| 59 | How does the site ensure that medicinal products are protected from harmful effects of light, temperature, moisture, or other external factors? | |  |  | |  | | |
| 60 | Is Particular attention paid to products where specific storage conditions are required? | |  |  | |  | | |
| 61 | Is stock rotation according to the expiry dates of batches of medicinal products performed ("first expired first out" ­ FEFO) basis? | |  |  | |  | | |
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| **SECTION 12 – Destruction of obsolete goods** | | | | | | | | |
| 62 | Is the destruction of medicinal products done in accordance with national or international requirements for disposal of such products? | |  |  | |  | | |
| 63 | Are records of all destroyed medicinal products maintained? | |  |  | |  | | |
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| **SECTION 13 – Picking** | | | | | | | | |
|  | What controls are in place to ensure the correct product is picked?  Is there a 4-eye principle in place? | |  |  | |  | | |
|  | How do you ensure appropriate shelf life remaining? | |  |  | |  | | |
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| **SECTION 14 – Complaints, Returns, Suspected Falsified Medicines and Medicinal Product Recall** | | | | | | | | |
|  | Are there procedures in place to manage complaints, returns and recalls? | |  |  | |  | | |
|  | Are all complaints, returns and recalls recorded? | |  |  | |  | | |
|  | Are relevant authorities informed about recalls? | |  |  | |  | | |
|  | Is the effectiveness of the recall system evaluated? Are mock recalls performed? | |  |  | |  | | |
|  | Does the site have a procedure in place which defines that any suspected falsified medicinal products found in the supply chain are immediately physically and securely segregated from legitimate medicinal products? | |  |  | |  | | |
|  | | | | | | | | |
| **SECTION 14 – Outsourced Activities** | | | | | | | | |
|  | Are there contracts in place defining responsibilities for each party? | |  |  | |  | | |
|  | Is an audit of the Contract Acceptor performed before the beginning of the outsourced activities? | |  |  | |  | | |
|  | Do you have Quality Agreements in place with all your critical suppliers? | |  |  | |  | | |
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| **SECTION 15 – Self Inspections** | | | | | | | | |
|  | Has the site implemented a self-­ inspection programme is to cover all aspects of GDP and compliance within a defined time frame? | |  |  | |  | | |
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| **SECTION 15 – Transportation** | | | | | | | | |
|  | How is it ensured that required storage conditions are maintained during transportation? | |  |  | |  | | |
|  | Does the site check if 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? | |  |  | |  | | |
|  | Are procedures in place for the operation and maintenance of all vehicles and equipment, including cleaning and safety precautions? | |  |  | |  | | |
|  | Are validated temperature control systems (e.g. thermal packaging, temperature-controlled containers, and refrigerated vehicles) used to ensure correct transport conditions? | |  |  | |  | | |
|  | Are the delivery drivers (including contract drivers) trained in the relevant areas of GDP? | |  |  | |  | | |
|  | How is it ensured that deliveries made directly to the address stated on the delivery note? | |  |  | |  | | |
|  | Do you use 3rd party contractors to transport product? (outsourced) | |  |  | |  | | |
|  | Have the delivery routes been risk assessed to determine where temp controls are required? | |  |  | |  | | |
|  | Is the equipment used for temp monitoring maintained and calibrated? How? | |  |  | |  | | |
|  | Are there dedicated vehicles used? | |  |  | |  | | |
|  | If not, are procedures in place to ensure quality is not compromised? | |  |  | |  | | |
|  | Are storage hubs used? Is so, how do you ensure temp monitoring, cleanliness and security of intermediate storage facilities. | |  |  | |  | | |
|  | Has temp mapping been carried out on vehicles, taking into account seasonal variations? | |  |  | |  | | |
|  | Do you use insulated boxes? | |  |  | |  | | |
|  | Has the staff been trained for the assembly of insulated boxes and use/reuse of cool packs (if applicable) | |  |  | |  | | |
|  | For container loading/shipment is there a check list for final inspection? | |  |  | |  | | |
|  | Are special transport conditions stated on the label where necessary? | |  |  | |  | | |
|  | Are the temperature/humidity controllers of vehicles or transport containers validated? | |  |  | |  | | |
|  | Are data loggers used during shipment?  Is the data from these loggers reviewed and kept? | |  |  | |  | | |
|  | Is the integrity of goods checked before unloading at the destination? | |  |  | |  | | |
|  | Is there an inspection made of the transport equipment cleanliness before loading? | |  |  | |  | | |
|  | Are transport regulations applied? | |  |  | |  | | |
|  | | | | | | | | |
| Completed by: | |  | | |  | |  | Signature: |
| Job Title: | |  | | |  | |  | Date: |