**Please email to** [**medicines@jolinda.co.uk**](mailto:medicines@jolinda.co.uk)

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| **PART 1 TO BE COMPLETED BY THE SUPPLIER** |

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| --- | --- | --- | --- | --- | --- | --- |
| **Full Legal Company Name** | | | | | | |
|  | | | | | | |
| **Company Registration Number & Date Company Formed / Start of Trading** | | | | | | |
|  | | | | | | |
| **Trading Name (if different from above)** | | | | | | |
|  | | | | | | |
| **Full Postal Address:** | **Post Code:** | | | | | |
| **Contact Name:** |  | | | **Tel No:** | |  |
| **e-mail:** |  | | | **Fax No:** | |  |
| **Out of Hours Contact:**  **For urgent recalls** | **Name**  **Email:** | | | **Tel No:**  **Mobile no:** | |  |
| **Web Address** |  | | |  | |  |
| **VAT No:** |  | | |  | |  |
| **Opening Hours** |  | | |  | |  |
| **Accounts Department (if different from above)** | | | | | | |
| **Address:** | | **Post Code:** | | | | |
| **Contact Name:** | |  | | **Tel No:** | |  |
| **e-mail:** | |  | | **Fax No:** | |  |
| **Wholesaler**  **Please attach copy of all licenses & GDP Certificate (all pages)**  **NOT EUDRA COPY** | | **☐** | **Licensed Product Categories**  **Please tick all that apply** | | **Authorised Wholesale Operations**  **Please tick all that apply** | |
| **WDA No or equivalent:**  **Site No:** | | | **☐ POM**  **☐ P**  **☐ GSL**  **☐ Unlicensed Medicines**  **☐ Cold Chain**  **☐ Blood Products**  **☐ Immunological Products**  **☐ With a UK, GB or NI MA, an article 126a authorisation a cert of reg or traditional herbal reg.**  **☐ Without a UK, GB or NI MA, an article 126a authorisation a cert of reg or traditional herbal reg.**  **☐ Without a UK, GB or NI MA, an article 126a authorisation a cert of reg or traditional herbal reg.in the UK & not intended for the UK market.** | | **☐ Procurement**  **☐ Supply**  **☐ Holding**  **☐ Export** | |
| **GDP Cert No:**  **Expiry date:** | | |
| **Responsible Person:**  **Email:** | | | **Other licenses (e.g. MS ‘Specials”)** | |
| **Technical Agreement Required?** | | | **☐YES**  **☐NO** | | **If YES please complete &**  **return with this form.** | |
| **TSE Compliance for Unlicensed medicine.**  **EU/EEA Suppliers**  **Do all products you sell to JMSL hold an MA in the country of origin within the EU/EEA?** | | | **☐YES**  **☐NO**  **If no please list each product & send authorised TSE Compliance Certificate / document for each product.** | |  | |
| **TSE Compliance for Unlicensed medicine.**  **Suppliers outside EU/EEA** | | | **Please list each product sold & send authorised TSE Compliance Certificate / document for each.** | |  | |

**QUALITY MANAGEMENT SYSTEMS (QMS) TO BE COMPLETED BY QP/RP/REGULATORY PERSONNEL**

**Please confirm YES/NO TO THE FOLLOWING QUESTIONS**

|  |  |
| --- | --- |
| **QUALITY MANAGEMENT SYSTEMS** |  |
| **Quality Manual/Policy & QMS system in place?** |  |
| **Documented deviations/CAPA system in place?** |  |
| **Documented change control system in place?** |  |
| **Documented risk management system in place?** |  |
| **Documented management review system in place?** |  |
| **PERSONNEL** |  |
| **Job descriptions in place for key personnel?** |  |
| **Procedures in place for receiving advice & comments from the RP?** |  |
| **Training program in place for all employees?** |  |
| **Good Distribution/Manufacturing Practice training conducted annually?** |  |
| **PREMISES & EQUIPMENT** |  |
| **Cleaning procedures in place & documented?** |  |
| **Pest control procedure in place & documented?** |  |
| **Storage temperatures monitored & controlled with alarms in case of excursions in all storage areas?** |  |
| **Storage areas temperatures mapped periodically?** |  |
| **Temperature monitoring equipment maintained & calibrated annually, with records kept?** |  |
| **Segregated, clearly marked areas for saleable & non-saleable stock?** |  |
| **Receiving/dispatch areas protect products from prevailing weather?** |  |
| **Security system in place to prevent unauthorised access to restricted areas?** |  |
| **Back up facility/plans in the event of power failure?** |  |
| **Qualification & validation system in place for key equipment?** |  |
| **Computer systems have individual passwords and restricted access?** |  |
| **Key equipment maintained & serviced periodically, with records kept?** |  |
| **DOCUMENTATION** |  |
| **SOP/KEY procedures/documents approved by the RP/QP/RPi** |  |
| **SOP/Key procedures version controlled with restricted access to master documents?** |  |
| **Staff have adequate training in good documentation practice?** |  |
| **Records & documentation used are stored according to regulations?** |  |
| **OPERATIONS** |  |
| **Procedures in place to ensure medicinal products are purchased from genuine suppliers?** |  |
| **Approved suppliers list maintained?** |  |
| **Procedures in place to ensure medicinal products are only sold to those authorised or entitled to receive them?** |  |
| **Approved customer list maintained?** |  |
| **Verification & due diligence checks performed on suppliers/customers?** |  |
| **System in place for checking all incoming goods for falsified medicine, tampering, damage & temperature?** |  |
| **System in place for the Falsified Medicines Directive (FMD)?** |  |
| **System in place for dealing with expired stock/stock nearing expiry?** |  |
| **Quarantine areas in place for stock issues?** |  |
| **Procedures in place for the destruction of medicinal products?** |  |
| **Procedure in place to ensure that the correct goods are supplied?** |  |
| **COMPLAINTS,RETURNS,SUSPECTED FALSIFIED MEDICINES & RECALLS** |  |
| **Documents complaints procedure?** |  |
| **Documented returns procedure?** |  |
| **Documented procedure in place for recorded suspected falsified medicinal products?** |  |
| **Documented recall procedure in place?** |  |
| **Perform periodic mock recalls for when genuine recalls have not occurred?** |  |
| **OUTSOURCED ACTIVITIES** |  |
| **Documented procedures in place for outsourced activities/** |  |
| **Technical Agreements (TA) in place for any outsourced activities which are reviewed regularly?** |  |
| **Conduct audits on contractors?** |  |
| **SELF-INSPECTIONS** |  |
| **Programme in place for performing self-inspections?** |  |
| **Self-Inspections performed annually?** |  |
| **TRANSPORTATION** |  |
| **Procedures in place to cover Transportation and packaging?** |  |
| **Procedures in place to cover transportation of temperature-sensitive products?** |  |
| **Temperature-controlled transport used?** |  |
| **Risk Assessments in place for transport routes?** |  |
| **Technical agreements in place with 3rd party transport providers?** |  |
| **Perform audits on Transporters?** |  |
| **GENERAL** |  |
| **If we were to conduct an on-site GDP audit of your premises what notice period would be required?** |  |

|  |  |
| --- | --- |
| **Bank Details** | **NEW ACCOUNTS ONLY** |
| **Account Name** |  |
| **Bank Address** |  |
| **Sort Code** |  |
| **Account Number** |  |
| **IBAN** |  |
| **BIC** |  |
| **SWIFT** |  |
| **Account Currency** |  |

|  |  |
| --- | --- |
| **Trade References (please supply two)** | **NEW ACCOUNTS ONLY** |
| **Company Name** |  |
| **Address** |  |
| **Contact name and Position** |  |
| **Contact Phone / Email Address** |  |
| **Company Name** |  |
| **Address** |  |
| **Contact name and Position** |  |
| **Contact Phone / Email Address** |  |

**A Company Director or Partner, QP or RP must complete the section below**

**Declaration**

**I am authorised to sign and open/verify an account with Jolinda Medical Supplies Ltd and declare that the information provided on this supplier form is complete and accurate and agree to abide by and accept their terms & conditions of trading.**

**Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Position \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **PART 2 FOR OFFICE USE ONLY** |

**FINAL APPROVAL TO BE COMPLETED BY THE JMSL RESPONSIBLE PERSON**

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| --- | --- | --- | --- |
| **Supplier Risk Assessment** | | | |
|  | | | |
| **RESPONSIBLE PERSON APPROVAL** | | | |
| **Approved** | **Name:** | **Signature:** | **Date:** |