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| **Supplier Vendor Qualification Questionnaire** |

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| **Introduction** |
| Consumer Healthcare Products Australia (CHP Australia) and Complementary Medicines Australia (CMA) have jointly developed this questionnaire in consultation with member companies.  This questionnaire is intended for agents, brokers, distributers and suppliers of active and excipient raw materials. It is site specific and has been designed to simplify and streamline the collection of information in relation to vendor qualification activities.  This questionnaire should be updated when any information changes or every three years.  Your assistance in completing this questionnaire will enable vendor qualification activities to be undertaken in compliance with current Australian regulatory requirements and help maintain the quality and safety of medicines produced and supplied in Australia. |

|  |  |  |
| --- | --- | --- |
| **1** | **Company and Contact Details** | |
| 1.1 | Company Name: |  |
|  | This document was completed by: | |
|  | Signature: |  |
|  | Name: |  |
|  | Title: |  |
|  | Date: |  |
|  |  | |
| 1.2 | Office address and contact details: | |
|  | Address: |  |
|  | Primary contact: | |
|  | Name: |  |
|  | Title: |  |
|  | Phone: |  |
|  | Facsimile: |  |
|  | E-mail: |  |
|  | Website: |  |
|  |  | |
| 1.3 | Warehouse address and contact details: | |
|  | Address: |  |
|  | Primary contact: | |
|  | Name: |  |
|  | Title: |  |
|  | Phone: |  |
|  | Facsimile: |  |
|  | E-mail: |  |
|  |  | |
| 1.4 | Contact details for quality and warehousing: | |
|  | Head of quality: | |
|  | Name: |  |
|  | Title: |  |
|  | Qualifications: |  |
|  | Experience: |  |
|  |  | |
|  | Head of warehousing: | |
|  | Name: |  |
|  | Title: |  |
|  | Qualifications: |  |
|  | Experience: |  |

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| 2 | | Organisation Structure, Personnel and Training | | | | | |
| 2.1 | | Do you have an organisational chart? | | | | | |
|  | | Yes | No | | | | |
|  | | If yes, please provide a copy of the organisational chart. | | | | | |
|  | |  | | | | | |
| 2.2 | | Do you have position descriptions? | | | | | |
|  | | Yes | No | | | | |
|  | | If yes, please provide a copy of the position descriptions for the head of quality and warehousing. | | | | | |
|  | |  | | | | | |
| 2.3 | | Is the quality department independent of sales? | | | | | |
|  | Yes | | | | | No | Not applicable |
|  | |  | | | | | |
| 2.4 | | Please confirm the approximate number of employees in each of the following areas? | | | | | |
|  | | Quality: | | |  | | |
|  | | Sales: | | |  | | |
|  | | Warehousing: | | |  | | |
|  | |  | | | | | |
| 2.5 | | Do you have specific health requirements for employees and contractors? | | | | | |
|  | | Yes | No | | | | |
|  | | If yes, please explain the specific health requirements for employees and contractors. | | | | | |
|  | |  | | | | | |
|  | |  | | | | | |
| 2.6 | | Do you have specific dress regulations for employees and contractors? | | | | | |
|  | | Yes | No | | | | |
|  | | If yes, please explain the specific dress regulations for employees and contractors. | | | | | |
|  | |  | | | | | |
|  | |  | | | | | |
| 2.7 | | Do you have procedures for training? | | | | | |
|  | | Yes | No | | | | |
|  | |  | | | | | |
| 2.8 | | Do you clearly identify the training requirements for employees and contractors? | | | | | |
|  | | Yes | No | | | | |
|  | |  | | | | | |
| 2.9 | | Do you provide quality awareness training for employees and contractors? | | | | | |
|  | | Yes | No | | | | |
|  | |  | | | | | |
| 2.10 | | How is training conducted and how often? | | | | | |
|  | |  | | | | | |
|  | |  | | | | | |
| 2.11 | | Do you verify training of employees and contractors by testing? | | | | | |
|  | | Yes | No | | | | |
|  | |  | | | | | |
| 2.12 | | Do you maintain training records for employees and contractors? | | | | | |
|  | | Yes | | No | | | |
|  | |  | | | | | |

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| **3** | **Capabilities and Licencing** | | | | | | | | | | |
| 3.1 | Do you maintain local inventory of raw materials? | | | | | | | | | | |
|  | Yes | | | | No | | | | | | |
|  |  | | | | | | | | | | |
| 3.2 | Do you have local warehousing facilities? | | | | | | | | | | |
|  | Yes | | | | No | | | | | | |
|  | If yes, do you sub-contract the warehousing? | | | | | | | | | | |
|  | Yes | | | | No | | | | | | |
|  |  | | | | | | | | | | |
| 3.3 | What types of products do you store at the site? | | | | | | | | | | |
|  | Active pharmaceutical ingredients | | Pharmaceutical excipients | | | | Herbal raw materials | | Nutritional raw materials | | |
|  | Cosmetic raw materials | | Industrial raw materials | | | | Sterile products | | Finished products (liquids/creams) | | |
|  | Finished products (solid) | | Foods | | | | Controlled substances | | Veterinary products | | |
|  | Products with high illicit value | | Agricultural raw materials | | | | Other | |  | | |
|  | Please provide details of other products you store at the site. | | | | | | | | | | |
|  |  | | | | | | | | | | |
|  |  | | | | | | | | | | |
| 3.4 | Do you store any of the following classes of products at the site? | | | | | | | | | | |
|  | Antiobiotics | | Betalactams | | | | Cephalosporins | | Pesticides | | |
|  | Cytotoxics | | Genotoxics | | | | Hormones | | Herbicides | | |
|  | Vaccines | | Steroids | | | | Infectious agents | | Fungicides | | |
|  |  | | | | | | | | | | |
| 3.5 | Do you repackage raw materials into smaller pack sizes? | | | | | | | | | | |
|  | Yes | | | | No | | | | | | |
|  | If yes, please explain in detail. | | | | | | | | | | |
|  |  | | | | | | | | | | |
|  |  | | | | | | | | | | |
| 3.6 | Do you relabel or overlabel raw materials? | | | | | | | | | | |
|  | Yes | | | | No | | | | | | |
|  | If yes, please explain in detail. | | | | | | | | | | |
|  |  | | | | | | | | | | |
|  |  | | | | | | | | | | |
| 3.7 | Do you sample or test raw materials? | | | | | | | | | | |
|  | Yes | | | | No | | | | | | |
|  | If yes, please explain in detail. | | | | | | | | | | |
|  |  | | | | | | | | | | |
|  |  | | | | | | | | | | |
| 3.8 | Is the site licensed/certified by any of the following authorities? If yes, please provide a copy of any current licence/certification. | | | | | | | | | | |
|  | **Authority** | | | | | **Licence or Certification Number** | | **Scope of Licence or Certification** | | **Date of Last Inspection** | |
|  | Therapeutic Goods Administration (TGA) | | | | |  | |  | |  | |
|  | International Standards Organisation (ISO) | | | | |  | |  | |  | |
|  | State Department of Health | | | | |  | |  | |  | |
|  | Other | | | | |  | |  | |  | |
|  | Please provide details of other licences/certifications. | | | | | | | | | | |
|  |  | | | | | | | | | | |
|  |  | | | | | | | | | | |
| 3.9 | Are you willing to undergo an audit or inspection? | | | | | | | | | | |
|  | Yes | | | | No | | | | | | |
|  |  | | | | | | | | | | |
| 3.10 | Have you been audited by any other companies? | | | | | | | | | | |
|  | Yes | | | | No | | | | | | |
|  | If yes, are you prepared to disclose the companies? | | | | | | | | | | |
|  | Yes | | | | No | | | | | | |
|  | If yes, please provide details of the companies and the dates of the last audits. | | | | | | | | | | |
|  | **Company Name** | | | | | | | | | | **Date of Last Inspection** |
|  |  | | | | | | | | | |  |
|  |  | | | | | | | | | |  |
|  |  | | | | | | | | | |  |
|  | |  | | | | | | | | | |
| 3.11 | | Do you have general and product liability insurance? | | | | | | | | | |
|  | | Yes | | No | | | | | | | |
|  | | If yes, please provide a summary of the insurance held, including the level of coverage. | | | | | | | | | |
|  | |  | | | | | | | | | |

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| **4** | **Buildings and Facilities** | | | | | |
| 4.1 | How long have you been located at the site? | | | | | |
|  |  | | | | | |
|  |  | | | | | |
| 4.2 | What is the approximate size of the site in square metres? | | | | | |
|  |  | | | | | |
|  |  | | | | | |
| 4.3 | How is access to the site controlled? | | | | | |
|  |  | | | | | |
|  |  | | | | | |
| 4.4 | What is the approximate size of the facility in square metres? | | | | | |
|  |  | | | | | |
|  |  | | | | | |
| 4.5 | What is the approximate age of the facility, and when where the last upgrades? | | | | | |
|  |  | | | | | |
|  |  | | | | | |
| 4.6 | What type of development surrounds the site? | | | | | |
|  | Heavy industrial | Light industrial | | Rural | | Residential |
|  |  | | | | | |
| 4.7 | Do you have an air handling system? | | | | | |
|  | Yes | | No | | | |
|  | If yes, please provide a diagram of the air handling system, and confirm the operational parameters including temperature, humidity, air change rates and filter specifications. | | | | | |
|  |  | | | | | |
|  |  | | | | | |
| 4.8 | Do you control temperature? | | | | | |
|  | Yes | | No | | | |
|  |  | | | | | |
| 4.9 | Do you monitor temperature? | | | | | |
|  | Yes | | No | | | |
|  | If yes, please provide a copy of the procedures for monitoring temperature, and explain how monitoring is performed and reviewed. | | | | | |
|  |  | | | | | |
|  |  | | | | | |
| 4.10 | Do you control relative humidity? | | | | | |
|  | Yes | | No | | | |
|  |  | | | | | |
| 4.11 | Do you monitor relative humidity? | | | | | |
|  | Yes | | No | | | |
|  | If yes, please provide a copy of the procedures for monitoring relative humidity, and explain how monitoring is performed and reviewed. | | | | | |
|  |  | | | | | |
|  |  | | | | | |
| 4.12 | Do you use refrigerated storage? | | | | | |
|  | Yes | | No | | | |
|  | If yes, do you monitor temperature? | | | | | |
|  | Yes | | No | | | |
|  | If yes, please provide a copy of the procedures for monitoring temperature, and explain how monitoring is performed and reviewed. | | | | | |
|  |  | | | | | |
|  | If yes, do you have an alarmed monitoring system? | | | | | |
|  | Yes | | No | | | |
|  | If yes, please explain how the alarmed monitoring system operates. | | | | | |
|  |  | | | | | |
|  |  | | | | | |
| 4.13 | Are drains and wastes designed with adequate air breaks to prevent back flushing or siphoning of waste? | | | | | |
|  | Yes | | No | | | |
|  |  | | | | | |
| 4.14 | Are pipes and services clearly labelled? | | | | | |
|  | Yes | | No | | | |
|  |  | | | | | |
| 4.15 | Do you control raw material status? | | | | | |
|  | Yes (manual) | | Yes (computerised) | | No | |
|  |  | | | | | |
| 4.16 | Do you have clearly designated approved, quarantined and rejected areas? | | | | | |
|  | Yes | | No | | | |
|  |  | | | | | |
| 4.17 | Do you receive deliveries from bulk tankers? | | | | | |
|  | Yes | | No | | | |
|  | If yes, do you have procedures and secured couplings to minimise the risk of incorrect coupling and unloading of deliveries from bulk tankers? | | | | | |
|  | Yes | | No | | | |
|  |  | | | | | |
| 4.18 | Are bulk tankers dedicated? | | | | | |
|  | Yes | | No | | | |
|  | If no, is a cleaning certificate required to be provided with each delivery? | | | | | |
|  | Yes | | No | | | |
|  |  | | | | | |
| 4.20 | Do you have procedures for pest control? | | | | | |
|  | Yes | | No | | | |
|  | If yes, please provide a copy of the pest control procedures, and confirm what pesticides are approved for use. | | | | | |
|  |  | | | | | |
|  |  | | | | | |
| 4.21 | Do you have specific controls on eating and smoking? | | | | | |
|  | Yes | | No | | | |
|  | If yes, please explain the specific controls on eating and smoking. | | | | | |
|  |  | | | | | |
|  |  | | | | | |
| 4.22 | Are toilets, change rooms and eating areas separate from storage areas and maintained in a sanitary condition? | | | | | |
|  | Yes | | No | | | |
|  |  | | | | | |
| 4.23 | What is the active ingredient in the soap/disinfectant provided in the toilets and change rooms? | | | | | |
|  |  | | | | | |
|  |  | | | | | |
| 4.24 | Do you have appropriately shielded lighting? | | | | | |
|  | Yes | | No | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **5** | **Materials Management** | | |
| 5.1 | Do you assign goods receivable numbers for raw materials? | | |
|  | Yes | No | |
|  | If yes, please explain how goods receivable numbers are assigned, and what the goods receivable numbers look like. | | |
|  |  | | |
|  |  | | |
| 5.2 | Do you follow the principles of first in first out (FIFO) or first expired first out (FEFO) stock rotation? | | |
|  | Yes (manual) | Yes (computerised) | No |
|  |  | | |
| 5.3 | Do you have a materials location system? | | |
|  | Yes (manual) | Yes (computerised) | No |
|  |  | | |
| 5.4 | Do you store more than one material per location? | | |
|  | Yes | No | |
|  |  | | |
| 5.5 | Do you guarantee to supply raw material with an expiry date greater than 12 months? | | |
|  | Yes | No | |
|  |  | | |
| 5.6 | Do you have procedures to notify customers in advance of late deliveries? | | |
|  | Yes | No | |
|  |  | | |
| 5.7 | Do you have procedures to ensure that unapproved raw material is not shipped to customers? | | |
|  | Yes | No | |
|  |  | | |
| 5.8 | Do you have procedures for handling rejected and returned raw material? | | |
|  | Yes | No | |

|  |  |  |  |
| --- | --- | --- | --- |
| **6** | **Quality Management** | | |
| 6.1 | Do you have a quality system? | | |
|  | Yes | No | |
|  | If yes, please provide a brief overview of the quality system. | | |
|  |  | | |
|  |  | | |
| 6.2 | Do you have a quality manual? | | |
|  | Yes | No | |
|  | If yes, please provide the table of contents of the quality manual. | | |
|  |  | | |
| 6.3 | Do you have procedures for environmental protection? | | |
|  | Yes | No | |
|  |  | | |
| 6.4 | Do you have procedures for disaster recovery to deal with man-made and/or natural disasters? | | |
|  | Yes | No | |
|  |  | | |
| 6.5 | Do you undertake regular reviews of the quality system? | | |
|  | Yes | No | |
|  | If yes, please provide details of the frequency of the reviews and what is reviewed. | | |
|  |  | | |
|  |  | | |
| 6.6 | Do you have a continuous quality improvement program? | | |
|  | Yes | No | |
|  |  | | |
| 6.7 | Do you have standard operating procedures? | | |
|  | Yes | No | |
|  | If yes, please provide a list of the standard operating procedures. | | |
|  |  | | |
| 6.8 | Who approves standard operating procedures? | | |
|  |  | | |
|  |  | | |
| 6.9 | Do you have procedures for change control? | | |
|  | Yes | No | |
|  |  | | |
| 6.10 | Do you have procedures for investigating non conformances? | | |
|  | Yes | No | |
|  |  | | |
| 6.11 | Do you have a non conformance database? | | |
|  | Yes | No | |
|  |  | | |
| 6.12 | Do you have procedures for corrective action and preventative action? | | |
|  | Yes | No | |
|  |  | | |
| 6.13 | Do you have a corrective action and preventative action database? | | |
|  | Yes | No | |
|  |  | | |
| 6.14 | Do you have procedures for risk management? | | |
|  | Yes | No | |
|  |  | | |
| 6.15 | Do you have procedures for internal and external audits? | | |
|  | Yes | No | |
|  | If yes, please provide details of the frequency of audits, and explain what is reviewed. | | |
|  |  | | |
|  |  | | |
| 6.16 | Are the results of internal and external audits documented and reviewed by management? | | |
|  | Yes | No | |
|  |  | | |
| 6.17 | Are corrective actions resulting from internal and external audits documented and verified for effectiveness? | | |
|  | Yes | No | |
|  |  | | |
| 6.18 | Do you have procedures for monitoring and reviewing manufacturers performance? | | |
|  | Yes | No | |
|  |  | | |
| 6.19 | Do you have procedures in place to ensure that the manufacturer and the customer have agreed to any changes to specifications prior to them being implemented? | | |
|  | Yes | No | |
|  |  | | |
| 6.20 | Do you agree to provide prior notification before any of the following changes are implemented? | | |
|  | Change in the manufacturer. | | Yes  No |
|  | Change in the method of manufacture. | | Yes  No |
|  | Change in the manufacturing site. | | Yes  No |
|  | Change in the registration/licensing status of the site. | | Yes  No |
|  | Change in the raw material specifications. | | Yes  No |
|  | Change in the analytical methods. | | Yes  No |
|  |  | | |
| 6.21 | Do you perform trend analysis on raw materials? | | |
|  | Yes | No | |
|  |  | | |
| 6.22 | Do you conduct product quality reviews on raw materials in accordance with ICH Q7A Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients or equivalent? | | |
|  | Yes | No | |
|  |  | | |
| 6.23 | Do you retain retention samples of each lot/batch of raw material? | | |
|  | Yes | No | |
|  | If yes, please confirm how long retention samples are retained. | | |
|  |  | | |

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| --- | --- | --- | --- | --- | --- |
| **7** | **Packaging, Storage and Distribution** | | | | |
| 7.1 | Do you have easily identifiable security seals or tape on each container of raw material to ensure tampering can be recognised? | | | | |
|  | Yes | | No | | |
|  | If yes, please supply a sample or picture of the tamper evident seals or tape. | | | | |
|  |  | | | | |
| 7.2 | Please provide details of what information is included on printed packaging and labelling? | | | | |
|  |  | | | | |
|  |  | | | | |
| 7.3 | How are raw materials transported to Australia? | | | | |
|  | Air | | Sea | | |
|  | Please explain in detail. | | | | |
|  |  | | | | |
|  |  | | | | |
| 7.4 | How are raw materials transported within Australia? | | | | |
|  | Air | Road | | Sea | Train |
|  | Please explain in detail. | | | | |
|  |  | | | | |
|  |  | | | | |
| 7.5 | Do you undertake any vendor assurance activities on the transport companies used? | | | | |
|  | Yes | | No | | |
|  |  | | | | |
| 7.6 | Do you have a list of approved transport companies? | | | | |
|  | Yes | | No | | |
|  |  | | | | |
| 7.7 | Have transport validation trials been conducted on the transportation methods used? | | | | |
|  | Yes | | No | | |
|  |  | | | | |
| 7.8 | Do you retain the transport records for raw materials? | | | | |
|  | Yes | | No | | |
|  |  | | | | |
| 7.9 | Do you use refrigerated transport? | | | | |
|  | Yes | | No | | |
|  | If yes, do you monitor temperature? | | | | |
|  | Yes | | No | | |
|  | If yes please provide a copy of the procedure for monitoring temperature, and explain how monitoring is performed and reviewed. | | | | |
|  |  | | | | |
|  |  | | | | |
| 7.10 | Do you document the supply chain? | | | | |
|  | Yes | | No | | |
|  | If yes, please provide details of how the supply chain is documented. | | | | |
|  |  | | | | |
|  |  | | | | |
| 7.11 | Do you have procedures to ensure that raw materials are packaged, stored, handled and transported in such a way as to prevent contamination and damage? | | | | |
|  | Yes | | No | | |
|  |  | | | | |
| 7.12 | Do you store raw materials off the floor? | | | | |
|  | Yes | | No | | |
|  |  | | | | |
| 7.13 | What type of pallets are raw materials stored on? | | | | |
|  |  | | | | |
|  |  | | | | |
| 7.14 | Are pallets used for international transport only subject to heat treatment and stamped in accordance with the International Plant Protection Convention (IPCC) International Standards for Phytosanitary Measures (ISPM) No. 15 Regulation of Wood Packaging Material in International Trade? | | | | |
|  | Yes | | No | | |
|  |  | | | | |
| 7.15 | Please provide details of what type of heat or chemical treatment pallets used for local storage and transport are subjected to. | | | | |
|  |  | | | | |

|  |  |  |
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| **8** | **Complaints and Recalls** | |
| 8.1 | Do you have procedures for investigating customer complaints? | |
|  | Yes | No |
|  |  | |
| 8.2 | Do you have a complaints database? | |
|  | Yes | No |
|  |  | |
| 8.3 | Who is responsible for conducting customer complaint investigations? | |
|  |  | |
|  |  | |
| 8.4 | Do you provide a response to customer complaints? | |
|  | Yes | No |
|  |  | |
| 8.5 | Do you document the cause of the complaint and the corrective action taken in the response to the customer? | |
|  | Yes | No |
|  |  | |
| 8.6 | Do you retain customer complaint documents? | |
|  | Yes | No |
|  |  | |
| 8.7 | Does management review customer complaints? | |
|  | Yes | No |
|  |  | |
| 8.8 | Have there been any recalls in the last five years? | |
|  | Yes | No |
|  | If yes, please provide details of any recalls in the last five years. | |
|  |  | |
|  |  | |
| 8.9 | Do you have procedures for conducting recalls? | |
|  | Yes | No |
|  |  | |
| 8.10 | Who is responsible for recalls? | |
|  |  | |
|  |  | |
| 8.11 | Who has the final decision on whether a recall is initiated? | |
|  |  | |

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| References |
| Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8 [www.tga.gov.au/industry/manuf-medicines-cgwp-schedule2-3-4-8.htm](http://www.tga.gov.au/industry/manuf-medicines-cgwp-schedule2-3-4-8.htm)  FAQs for manufacturers, wholesalers and retailers  <https://www.health.nsw.gov.au/pharmaceutical/licences/Pages/faq-manufacturers-wholesalers-retailers.aspx>  PIC/S Guide to Good Manufacturing Practice for Medicinal Products Part I  [www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm](http://www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm)  PIC/S Guide to Good Manufacturing Practice for Medicinal Products Part II  [www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm](http://www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm)  Therapeutic Goods Administration (TGA)  [www.tga.gov.au](http://www.tga.gov.au) |

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| **Document Revision History** | | |
| **Date** | **Version** | **Changes** |
| 16/01/12 | 1 | First issue. |
| 4/08/14 | 2 | Question 3.3 updated to include additional product type.  Introduction updated to reflect name change of CHC to CMA. |
| 15/07/2019 | 3 | Introduction updated to reflect name change of ASMI to CHP Australia.  Update to Reference hyperlinks |