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| **Packaging Material Manufacturer 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 manufacturers of labels, printed and unprinted packaging 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. |

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| **1** | **Company and Contact Details** |
| 1.1 | Company Name: |       |
|  | This document was completed by: |
|  | Signature: |  |
|  | Name: |       |
|  | Title: |       |
|  | Date: |       |
|  |  |
| 1.2 | Manufacturing site address and contact details: |
|  | Address: |       |
|  | Primary contact: |
|  | Name: |       |
|  | Title: |       |
|  | Phone: |       |
|  | Facsimile: |       |
|  | E-mail: |       |
|  | Website: |       |
|  |  |
| 1.3 | Contact details for quality and manufacturing: |
|  | Head of quality: |
|  | Name: |       |
|  | Title: |       |
|  | Qualifications: |       |
|  | Experience: |       |
|  |  |
|  | Head of manufacturing: |
|  | 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 manufacturing. |
|  |  |
| 2.3 | Is the quality department independent of manufacturing? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 2.4 | Please confirm the approximate number of employees in each of the following areas? |
|  | Warehousing: |       |
|  | Manufacturing: |       |
|  | Quality: |       |
|  | Engineering/maintenance: |       |
|  |  |
| 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 good manufacturing practice (GMP), cleanliness and 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 Licensing** |
| 3.1 | What types of products do you manufacture at the site? |
|  | [ ]  Unprinted packaging material | [ ]  Printed packaging material | [ ]  Labels | [ ]  Other |
|  | Please provide details of other products you manufacture at the site. |
|  |       |
|  |  |
| 3.2 | 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** |
|  | [ ]  International Standards Organisation (ISO) |       |       |       |
|  | [ ]  Other |       |       |       |
|  | Please provide details of other licences/certifications. |
|  |       |
|  |  |
| 3.3 | Do you sub-contract any part of the manufacturing process? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of the manufacturing process that is sub-contracted and provide a copy of any current licence/certification. |
|  | **Step in Manufacture** | **Company Name** | **Authority** | **Licence or Certification Number** | **Scope of Licence or Certification** | **Date of Last Inspection** |
|  |       |       |       |       |       |       |
|  |       |       |       |       |       |       |
|  |       |       |       |       |       |       |
|  |  |
| 3.4 | If you sub-contract any part of the manufacture of the packaging material, how is the packaging material transported between sites?  |
|  |       |
|  |  |
| 3.5  | Are you willing to undergo an audit or inspection? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 3.6 | 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** |
|  |       |       |
|  |       |       |
|  |       |       |
|  |  |
| 3.7 | 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 | Do you have a Site Master File? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the Site Master File. |
|  | If no, can you provide a copy of the site and facility plan? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the site and facility plan. |
|  |  |
| 4.2 | How long have you been located at this site? |
|  |       |
|  |  |
| 4.3 | What is the approximate size of the site in square metres?  |
|  |       |
|  |  |
| 4.4 | How is access to the site controlled? |
|  |       |
|  |  |
| 4.5 | What is the approximate size of the facility in square metres?  |
|  |       |
|  |  |
| 4.6 | What is the approximate age of the facility, and when where the last upgrades? |
|  |       |
|  |  |
| 4.7  | What type of development surrounds the site?  |
|  | [ ]  Heavy industrial | [ ]  Light industrial | [ ]  Rural | [ ]  Residential |
|  |  |
| 4.8 | 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. |
|  |       |
|  |  |
| 4.9 | Are pipes and services clearly labelled? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.10 | Do you control packaging material status?  |
|  | [ ]  Yes (manual) | [ ]  Yes (computerised) | [ ]  No |
|  |  |
| 4.11 | Do you have clearly designated approved, quarantined and rejected areas? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.12 | Do you have secure storage for artwork and printing plates? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.13 | Do you have secure storage for printed packaging materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.14 | 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. |
|  |       |
|  |  |
| 4.15 | Do you have procedures for environmental monitoring? |
|  | [ ]  Yes | [ ]  No |
|  | If yes please provide a copy of the procedures for environmental monitoring, confirm the parameters that are monitored, and explain how environmental monitoring is performed and reviewed. |
|  |       |
|  |  |
| 4.16 | Do you have specific controls on eating and smoking? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of the specific controls on eating and smoking. |
|  |       |
|  |  |
| 4.17 | Are toilets, change rooms and eating areas separate from manufacturing areas and maintained in a sanitary condition? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.18 | Do you have signs erected in toilets and change rooms to instruct employees on appropriate hand washing techniques before starting or returning to work?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.19 | What is the active ingredient in the soap/disinfectant provided in the toilets and change rooms?  |
|  |       |
|  |  |
| 4.20 | Do you have appropriately shielded lighting? |
|  | [ ]  Yes | [ ]  No |

|  |  |
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| **5** | **Process Equipment** |
| 5.1 | Are process equipment contact surfaces designed and constructed not to be reactive or additive? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.2 | Are process equipment contact surfaces easily cleaned? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.3  | Do you have procedures for the following aspects of process equipment?  |
|  | Operation | [ ]  Yes | [ ]  No |
|  | Calibration | [ ]  Yes | [ ]  No |
|  | Cleaning | [ ]  Yes | [ ]  No |
|  | Maintenance | [ ]  Yes | [ ]  No |
|  |  |
| 5.4 | Do you keep records of the following maintenance activities for process equipment? |
|  | Calibration | [ ]  Yes | [ ]  No |
|  | Routine maintenance | [ ]  Yes | [ ]  No |
|  | Repairs | [ ]  Yes | [ ]  No |
|  | Modifications | [ ]  Yes | [ ]  No |
|  |  |
| 5.5 | Please indicate what process capabilities you have? |
|  | Blister foil printing | [ ]  Yes | [ ]  No |
|  | Label printing | [ ]  Yes | [ ]  No |
|  | Packaging printing | [ ]  Yes | [ ]  No |
|  | Glass moulding | [ ]  Yes | [ ]  No |
|  | Plastic blow moulding | [ ]  Yes | [ ]  No |
|  | Plastic injection moulding | [ ]  Yes | [ ]  No |
|  | Other | [ ]  Yes | [ ]  No |
|  | Please provide details of other process capabilities. |
|  |       |
|  |  |
| 5.6 | Please provide the title and reporting structure of the person in charge of maintenance? |
|  |       |
|  |  |
| 5.7 | Do you dedicate any process equipment to manufacture one packaging material? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.8  | Do you concurrently manufacture different packaging materials in a common area? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of how you minimise the risk of mix up. |
|  |       |
|  |  |
| 5.9 | Do you manufacture by lot or continuous process? |
|  | [ ]  Lot | [ ]  Continuous |
|  |  |
| 5.10 | Do you use electronic code readers for verifying printed packaging materials? |
|  | [ ]  Lot | [ ]  Continuous |
|  | If yes, please explain how electronic code readers operate. |
|  |       |
|  |  |
| 5.11 | Do the procedures for maintenance specify the lubricants that can be used on specific process equipment?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.12 | Do you approve lubricants prior to use?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.13 | Do the procedures for cleaning specify the method of preparation, expiry date and dilution rates for the cleaning and sanitising agents that can be used?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.14 | Do you approve the cleaning and sanitising agents prior to use?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.15 | Do you use statistical process control techniques in manufacturing? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.16 | Do you use metal detectors at any stage of manufacturing?  |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of what stage/s of manufacturing are they used and their limit of detection.  |
|  |       |

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| **6** | **Materials Management** |
| 6.1 | Do you follow the principles of first in first out (FIFO) or first expired first out (FEFO) stock rotation? |
|  | [ ]  Yes (manual) | [ ]  Yes (computerised) | [ ]  No |
|  |  |
| 6.2  | Do you have a materials location system? |
|  | [ ]  Yes (manual) | [ ]  Yes (computerised) | [ ]  No |
|  |  |
| 6.3 | Do you store more than one material per location? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 6.4 | Do you assign lot/batch numbers for packaging materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please explain how lot/batch numbers are assigned, and what the lot/batch numbers look like.  |
|  |       |
|  |  |
| 6.5 | Do you have procedures to notify customers in advance of late deliveries? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 6.6 | Do you have procedures to ensure that unapproved packaging material is not shipped to customers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 6.7 | Do you have procedures for handling rejected and returned packaging material? |
|  | [ ]  Yes | [ ]  No |

|  |  |
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| **7** | **Quality Management** |
| 7.1 | Do you have a quality system? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a brief overview of the quality system. |
|  |       |
|  |  |
| 7.2 | Do you have a quality manual? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide the table of contents of the quality manual. |
|  |  |
| 7.3 | Do you have procedures for environmental protection? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.4 | Do you have procedures for disaster recovery to deal with man-made and/or natural disasters? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.5 | 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. |
|  |       |
|  |  |
| 7.6 | Do you have a continuous quality improvement program? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.7 | Do you have standard operating procedures?  |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a list of the standard operating procedures. |
|  |       |
| 7.8 | Do you have specifications?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.9 | Who approves standard operating procedures and specifications?  |
|  |       |
|  |  |
| 7.10 | Do you have procedures for sampling starting materials and packaging materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.11 | Do you follow statistical sampling plans? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.12 | Who performs sampling?  |
|  |       |
|  |  |
| 7.13 | Do you have procedures for reviewing and updating procedures and specifications? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.14 | Do you have procedures for change control? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.15 | Do you have procedures for investigating non conformances? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.16 | Do you have a non conformance database? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.17 | Do you have procedures for corrective action and preventative action? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.18 | Do you have a corrective action and preventative action database? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.19 | 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. |
|  |       |
|  |  |
| 7.20 | Are the results of internal and external audits documented and reviewed by management. |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.21 | Are corrective actions resulting from internal and external audits documented and verified for effectiveness? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.22 | Do you have procedures in place to ensure that the distributor/trader and customer have agreed to any changes to specifications prior to them being implemented? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.23 | Do you agree to provide prior notification before any of the following changes are implemented?  |
|  | Change in the manufacturing site. | [ ]  Yes [ ]  No |
|  | Change in the packaging material specifications.  | [ ]  Yes [ ]  No |
|  |  |
| 7.24 | Do you have procedures in place for line clearance?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.25 | Do you have procedures in place for issuing artwork and printing plates? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.26 | Do you have procedures in place for disposal of obsolete artwork and printing plates? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.27 | Do you have procedures in place for design and revision of artwork and printing plates? |
|  | [ ]  Yes | [ ]  No |
|  |  |

|  |  |
| --- | --- |
| **8** | **Quality Control - General Starting Materials** |
| 8.1 | Do you ensure that certificates of analysis are supplied with every delivery of starting material? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.2 | Do you have specifications for starting materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, are these specifications available to customers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.3 | Do you have test procedures for starting materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, are these test procedures available to customers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.4 | Do you test starting materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.5 | Do you test every delivery of starting material? |
|  | [ ]  Yes | [ ]  No |
|  | If no, please provide details of what tests are performed on every delivery.  |
|  |       |
|  |  |
| 8.6 | Do you have procedures to allow reduced testing of starting materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the reduced testing procedures. |
|  |  |
| 8.7 | When reduced testing is performed, is it indicated on the certificate of analysis? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 8.8 | Are inspection and testing results for starting materials reviewed by qualified laboratory personnel? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.9 | Who has the authority to approve and reject starting materials? |
|  |       |
|  |  |
| 8.10 | Do you retain inspection and testing records for each delivery of starting material? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please confirm how long inspection and testing records are retained. |
|  |       |
|  |  |
| 8.11 | Do you retain retention samples of each delivery of starting material? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please confirm how long retention samples are retained. |
|  |       |
|  |  |
| 8.12 | Do you retain the certificates of analysis provided by suppliers? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please confirm how long certificates of analysis are retained. |
|  |       |
|  |  |
| 8.13 | Can you provide copies of inspection and testing records and certificates of analysis if requested? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.14 | Do you have procedures for maintaining traceability of starting materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.15 | Do you have procedures for receiving starting materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.16 | Do you have procedures for approving starting materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.17 | Do you have procedures for rejecting starting materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.18 | Do you have procedures for vendor assurance of starting material suppliers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.19 | Do you maintain a list of the vendor assurance status of starting material suppliers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.20 | Do you recover and reuse any starting materials in the manufacture of other packaging materials?  |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of any starting materials that are recovered and reused in the manufacture of other packaging materials, and explain what testing is undertaken. |
|  |       |
|  |  |
| 8.21 | Are rejected starting materials ever reprocessed and reused?  |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please explain how rejected starting materials can be reprocessed. |
|  |       |
|  |  |
| 8.22 | Do you use any form of sterilisation on starting materials?  |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details on what forms of sterilisation are used and whether it is indicated on certificates of analysis. |
|  |       |

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| **9** | **Quality Control - Packaging Materials** |
| 9.1 | Do you have specifications for raw materials? |
|  | [ ]  Yes | [ ]  No |
|   | If yes, are these specifications available to customers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 9.2 | Do you have test procedures for raw materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, are these test procedures available to customers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 9.3 | Do you test raw materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 9.4 | Do you test every lot/batch of raw material? |
|  | [ ]  Yes | [ ]  No |
|  | If no, please provide details of what tests are performed on every lot/batch.  |
|  |       |
|  |  |
| 9.5 | Do you have procedures to allow reduced testing of raw materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the reduced testing procedures.  |
|  |  |
| 9.6 | When reduced testing is performed, is it indicated on the certificate of analysis? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 9.7 | Are inspection and testing results for raw materials reviewed by qualified laboratory personnel? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 9.8 | Who has the authority to approve and reject raw materials? |
|  |       |
|  |  |
| 9.9 | Do you retain inspection and testing records for each lot/batch of raw material? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please confirm how long inspection and testing records are retained? |
|  |       |
|  |  |
| 9.10 | Do you retain retention samples of each lot/batch of raw material? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please confirm how long retention samples are retained. |
|  |       |
|  |  |
| 9.11 | Do you provide a Certificate of Analysis or Certificate of Conformance for every lot/batch? |
|  | [ ]  Yes | [ ]  No |

|  |  |
| --- | --- |
| **10** | **Packaging, Storage and Distribution** |
| 10.1 | How are packaging materials packaged? |
|  |       |
|  |  |
| 10.2 | Do you have easily identifiable security seals or tape on each container of packaging material to ensure tampering can be recognised? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please supply a sample or picture of the tamper evident seals or tape.  |
|  |  |
| 10.3 | Please provide details of what information is included on printed packaging and labelling? |
|  |       |
|  |  |
| 10.4 | Do you have procedures for the control, use and reconciliation of printed packaging and labelling? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the procedures for the control, use and reconciliation of printed packaging and labelling. |
|  |  |
| 10.5 | Do you have procedures to verify the accuracy of printed packaging and labelling? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the procedures to verify the accuracy of printed packaging and labelling. |
|  |  |
| 10.6 | Do you have procedures for minimising packaging and labelling errors? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the procedures for minimising packaging and labelling errors. |
|  |  |
| 10.7 | How are packaging materials transported to Australia? |
|  | [ ]  Air | [ ]  Sea |
|  | Please explain in detail. |
|  |       |
|  |  |
| 10.8 | How are packaging materials transported within Australia? |
|  | [ ]  Air | [ ]  Road | [ ]  Sea | [ ]  Train |
|  | Please explain in detail. |
|  |       |
|  |  |
| 10.9 | Do you undertake any vendor assurance activities on the transport companies used? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 10.10 | Do you have a list of approved transport companies? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 10.11 | Have transport validation trials been conducted on the transportation methods used? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 10.12 | Do you retain the transport records for packaging materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 10.13 | Do you document the supply chain? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of how the supply chain is documented. |
|  |       |
|  |  |
| 10.14 | Do you have procedures to ensure that packaging materials are packaged, stored, handled and transported in such a way as to prevent contamination and damage? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 10.15 | 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 |
|  |  |
| 10.16 | Please provide details of what type of heat or chemical treatment pallets used for local storage and transport are subjected to? |
|  |       |

|  |  |
| --- | --- |
| **11** | **Complaints and Recalls** |
| 11.1 | Do you have procedures for investigating customer complaints? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 11.2 | Do you have a complaints database? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 11.3 | Who is responsible for conducting customer complaint investigations? |
|  |       |
|  |  |
| 11.4 | Do you provide a response to customer complaints? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 11.5 | Do you document the cause of the complaint and the corrective action taken in the response to the customer? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 11.6 | Do you retain customer complaint documents? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 11.7 | Does management review customer complaints? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 11.8 | 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. |
|  |       |
|  |  |
| 11.9 | Do you have procedures for conducting recalls? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 11.10 | Who is responsible for recalls? |
|  |       |
|  |  |
| 11.11 | Who has the final decision on whether a recall is initiated? |
|  |       |
|  |  |

|  |  |
| --- | --- |
| **12** | **Laboratory** |
| 12.1 | Do you have procedures for the following aspects of laboratory equipment?  |
|  | Operation | [ ]  Yes | [ ]  No |
|  | Calibration | [ ]  Yes | [ ]  No |
|  | Cleaning | [ ]  Yes | [ ]  No |
|  | Maintenance | [ ]  Yes | [ ]  No |
|  |  |
| 12.2 | Do you keep records of the following maintenance activities for laboratory equipment? |
|  | Calibration | [ ]  Yes | [ ]  No |
|  | Routine maintenance | [ ]  Yes | [ ]  No |
|  | Repairs | [ ]  Yes | [ ]  No |
|  | Modifications | [ ]  Yes | [ ]  No |
|  |  |
| 12.3 | Are calibration standards used traceable to a recognised standard?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 12.4 | Do you record raw data in duplicate workbooks?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 12.5 | Do you undertake trend analysis on analytical results? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 12.6 | Do you have dedicated sampling facilities? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 12.7 | Please provide details of the laboratory capabilities you have? |
|  |       |
|  |  |
| 12.8 | Please provide details of the instrumentation capabilities you have? |
|  |       |

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| References |
| 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)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 | 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 |