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| **GMP/Quality/Technical Agreement - Finished Medicinal Product Manufacture**  An Industry Template for a GMP Agreement |
| Version 1.0  May 2025 |

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# Objective

## The purpose of this GMP/Quality/Technical Agreement Template is to define the Good Manufacturing Practice and [Marketing Authorisation](#_Glossary_of_terms) regulatory obligations and responsibilities of the [Contract Giver](#_Glossary_of_terms) and the [Contract Acceptor,](#_Glossary_of_terms) along with the necessary communication processes to fulfill the agreement. Where there are multiple parties to the agreement the responsibilities and obligations assigned must consistently apply to all the medicinal products supplied under the agreement as listed in [Appendix 3](#_Products_Subject_to). All [steps of manufacture](#_Glossary_of_terms) of a medicinal substance or medicinal product should be conducted under such an agreement.

## This template agreement is intended to be amended as the Contract Giver requires, to reflect the scope of outsourced works, providing all aspects are compliant with the requirements of Chapter 7 of the PICS PE-009 Guide to Good Manufacturing Practice for Medicinal Products (Part 1).

## A separate annex ([Annex 1](#_Annex_1._Steps) - Steps of Manufacture by site for each product) to the GMP Agreement Template is designed to provide clarity to the Authorised Person conducting the Batch Certification, identifying the sites of manufacture undertaking each step of manufacture. Where that step is required to be listed in the Marketing Authorisation (MA) it must be maintained consistent with the MA. Annex 1 is written on the assumption the full supply chain may be confidential to the sponsor and hence the signatories listed are just the sponsor and the authorised person. This is not intended to preclude additional signatories for transparency to each party to the agreement as necessary.

# Scope

## This agreement specifies the Good Manufacturing Practice and Marketing Authorisation obligations of the Contract Giver and Contract Acceptor for the relevant steps of manufacture relating to the products supplied listing in Appendix 3 – Products subject to the agreement to ensure clarity of responsibilities and effective communication processes.

## This agreement does not address the commercial arrangements, and the resulting financial and timeliness obligations and responsibilities. These will need to be addressed separately in a Commercial/Supply Agreement. This contract should however, describe clearly which party to the contract has responsibility for conducting each step of the outsourced activity. For example, knowledge management, technology transfer, validation, testing, manufacturing steps, supply chain, quality and purchasing of materials, storage and transportation, subcontracting.

# Parties to the Agreement

## This agreement is made by and between:

|  |  |  |  |
| --- | --- | --- | --- |
| Company Name | Contract Giver | Contract Acceptor 1 | Contract Acceptor 2 |
|  |  |  |
| Registered Office  and if different the manufacturer’s or laboratory’s site address |  |  |  |
| Administration Office |  |  |  |
| Telephone No. |  |  |  |
| ACN No. |  |  |  |
| Licence No. / GMP Clearance / TGA Client ID |  |  |  |

# Authorisation

|  |  |  |  |
| --- | --- | --- | --- |
| Authorised on  behalf of | Contract Giver | Contract Acceptor 1 | Contract Acceptor 2 |
| Name: |  |  |  |
| Title: |  |  |  |
| Signature: |  |  |  |
| Date: |  |  |  |

# Alteration, Validity and Termination

## The standard review period for this document is agreed at [X] years from the date of signing of the contract giver.

## The agreement is considered to come into effect from the last date of signing by all parties to the agreement.

## This agreement may only be updated with the mutual agreement of the parties demonstrated by

### revised Authorisation by each of the parties.

* updated version control of the document.
* Update to the Document Revision History under section 7.

## Issues which may trigger the need for review of the agreement for update include but are not limited to; update to the PIC/S Guide PE-009 to the current version, changes to the manufacturer’s GMP licence, changes to outsourced parties or activities.

## This agreement can be terminated by either party with an [X] month prior period of notice in writing, however ongoing responsibilities may extend past the termination of this agreement, for example, document retention, complaints, stability testing and results, as agreed.

## The appendices to this agreement may and should be independently updated by mutual agreement of the parties. E.g. Appendix 3 – Products subject to the agreement.

# Code of GMP Responsibility Tables

## Instructions for completion of the table.

* The list of responsibility areas provided in the template aims to be comprehensive.
* Each responsibility line description within the table in section 7 can only be assigned to one party. Assigning to more than one party creates ambiguity of responsibility.
* Where the description provided in the agreement can apply to more than one party, consider the task required of each party and insert additional line description(s) splitting the task to accurately reflect the responsibility of each party. Communication processes should also be included in the Responsibility Tables.
* Hyperlinks (blue underlined text) to the Glossary section are provided where a terminology is used for the first time to support common understanding.
* Further parties to the agreement may be included by inserting additional columns, however the responsibilities of each of the parties must be consistent with their roles in the manufacture of the products listed in Appendix 3.
* Some responsibility areas may not apply to all contractual arrangements and the agreement may be amended as appropriate, including deletion of particular responsibility areas (rows in the table).
* It is a useful exercise to work through the responsibility areas to understand which party needs to take responsibility for each of the obligations.

# GMP Responsibility Areas

| Responsibility Areas | Contract Giver | | Contract Acceptor 1 | | Contract Acceptor 2 |
| --- | --- | --- | --- | --- | --- |
| **MARKETING AUTHORISATION** | | | | | |
| Provision of Marketing Authorisation to the Authorised Person (AP) | |  | |  |  |
| Notification/confirmation of changes made to the Marketing Authorisation. | |  | |  |  |
| **WORK HEALTH AND SAFETY:** | | | | | |
| Provision to the Contract Acceptor(s) or nominated representative of all relevant information about the product which may pose a hazard to the premises, equipment, personnel, other materials or other products | |  | |  |  |
| Provision of material Safety Data Sheets (mSDS) for all raw materials | |  | |  |  |
| Provision of product Safety Data Sheets (pSDS) for all products | |  | |  |  |
| Retain copies of all mSDS and pSDS documents and provide updated information on request | |  | |  |  |
| **STARTING MATERIALS – Active & Excipients** | | | | |  |
| [Specification](#_Glossary_of_terms) and supply of raw materials – including pharmacopoeial/quality standard reference where practicable |  | |  | |  |
| Procurement and provision of specific materials (not procured by the bulk manufacturer) including vendor assurance approval. |  | |  | |  |
| Sampling, testing and release for use (as well as expiry/retest information) |  | |  | |  |
| Retention of test records and retention samples |  | |  | |  |
| Assessment/Qualification of starting material manufacturer and supply chain |  | |  | |  |
| Evaluation testing and approval for Release/Rejection/Quarantine of raw materials |  | |  | |  |
| Notification of change to materials due to sourcing or manufacturing changes |  | |  | |  |
| **STARTING MATERIALS –** [**Functional Packaging**](#_Glossary_of_terms) | | | | | |
| Provision of [packaging materials](#_Glossary_of_terms) |  | |  | |  |
| Design/identification of functional packaging materials |  | |  | |  |
| Preparation and maintenance of specification |  | |  | |  |
| [Approval](#_Glossary_of_terms) of specification/reference standard (where applicable) |  | |  | |  |
| [Authorisation](#_Glossary_of_terms) of specification/reference standard (where applicable) |  | |  | |  |
| Assessment/Qualification of packaging manufacturers and supply chain |  | |  | |  |
| Notification of change to packaging materials due to sourcing changes |  | |  | |  |
| Notification of change to packaging materials due to brand redesign or sustainability options |  | |  | |  |
| Confirmation of practicalities of packaging change |  | |  | |  |
| Evaluation and testing of packaging components and approval for use |  | |  | |  |
| Reference and/or Retention of samples and test records |  | |  | |  |
| **STARTING MATERIALS –** [**Printed Packaging**](#_Glossary_of_terms) | | | | | |
| Creation and approval of artwork |  | |  | |  |
| Confirmation/approval of artwork compliant with the Marketing Authorisation and the Labelling Order |  | |  | |  |
| Compliance of export label copy with the relevant legislation in the country of sale |  | |  | |  |
| Provision of colour standard on first run of printed materials |  | |  | |  |
| Preparation and maintenance of specification of printed packaging materials |  | |  | |  |
| Approval of specification of printed packaging materials |  | |  | |  |
| Authorisation of Specification |  | |  | |  |
| Notification of change to printed packaging materials due to regulatory requirement |  | |  | |  |
| Notification of changes to label due to redesign |  | |  | |  |
| Evaluation of printed packaging and approval for use |  | |  | |  |
| Retention of samples and test records |  | |  | |  |
| Disposal of superseded plates/cylinders |  | |  | |  |
| **WORK IN PROGRESS / BULK PRODUCT** | | | | | |
| Supply of Master Formula |  | |  | |  |
| Preparation and maintenance of Master Manufacturing Batch Processing Instruction/Record |  | |  | |  |
| Approval and confirmation of compliance with Marketing Authorisation of the Manufacturing Batch Processing Instruction/Record |  | |  | |  |
| Authorisation for use of the Manufacturing Batch Processing Instruction/Record |  | |  | |  |
| Supply of bulk Product Specification |  | |  | |  |
| Preparation and maintenance of Bulk Product Specification |  | |  | |  |
| Approval of bulk Product Specification compliance with Marketing Authorisation |  | |  | |  |
| Authorisation of Bulk Product Specification for use |  | |  | |  |
| **VALIDATION: TEST METHODS (Analytical, Microbiological, Biological, Physical)** | | | | | |
| Determination of test method requirements |  | |  | |  |
| Assignment of method |  | |  | |  |
| Assessment of method validity |  | |  | |  |
| Preparation of Validation Protocol |  | |  | |  |
| Approval of Validation Protocol |  | |  | |  |
| Authorisation of Validation Protocol for use |  | |  | |  |
| Preparation and provision of Validation Report |  | |  | |  |
| Approval of validation report |  | |  | |  |
| Preparation of justification for reduced validation e.g. due to compendial method, method transfer |  | |  | |  |
| Approval of justification for reduced validation |  | |  | |  |
| Preparation of justification for Analytical Method Product Grouping Validation |  | |  | |  |
| Acceptance of justification for Analytical Method Product Grouping Validation |  | |  | |  |
| **VALIDATION: PROCESS/CLEANING** | | | | | |
| Preparation of Validation Grouping Justifications |  | |  | |  |
| Approval of Validation Grouping Justifications |  | |  | |  |
| Preparation of Validation Protocols |  | |  | |  |
| Approval of Validation Protocols |  | |  | |  |
| Authorisation of Validation Protocols for use |  | |  | |  |
| Preparation and provision of Validation Report |  | |  | |  |
| Approval of Validation Reports |  | |  | |  |
| **PACKAGING OPERATION:** | | | | | |
| Provision of general packaging instructions |  | |  | |  |
| Preparation and maintenance of Master Packaging Instructions |  | |  | |  |
| Approval of Master Packaging Instructions compliant with Marketing authorisation (as applicable) |  | |  | |  |
| Authorisation of Master Packaging Instructions for use |  | |  | |  |
| Specification of batch coding/expiry format for finished product |  | |  | |  |
| Retention sample storage and management |  | |  | |  |
| Retention and retrieval of Packaging records for a period of [X] years |  | |  | |  |
| **QUALITY CONTROL TESTING AND REVIEW FOR PRODUCT RELEASE** | | | | | |
| Provision of Sampling Specifications and Methods for QC |  | |  | |  |
| Preparation of QC Specifications |  | |  | |  |
| Authorisation of QC Specifications |  | |  | |  |
| Preparation of QC Testing Methods |  | |  | |  |
| Authorisation of QC Testing Methods |  | |  | |  |
| Provision of analytical reference standard/s |  | |  | |  |
| QC testing to specifications |  | |  | |  |
| Preparation/Provision of Certificate of Analysis |  | |  | |  |
| Review of Batch records |  | |  | |  |
| **BATCH CERTIFICATION (Release for Supply):** | | | | |  |
| Provision of a diagram/table identifying all sites of manufacture involved in the steps of manufacture of each finished product to the AP responsible for finished product Batch Certification (See [Annex 1](#_Annex_1._Steps))  Where practical, include the sites of manufacture of [starting materials](#_Glossary_of_terms) and packaging materials and other materials |  | |  | |  |
| Review and confirm all aspects regarding the relevant steps of manufacture and control of the batch, according to the Marketing Authorisation including:   * deviations, OOS and OOT, non-conformance investigations, CAPA closures, * facility internal audits and outsourced utilities qualification/inspection reports, * environmental monitoring trends, complaints, change controls, validation, PQR's and ongoing stability compliance,   are current and in compliance, and any other issues, as stipulated in the authorised person responsibilities and duties in the PIC/S Guide and TGA Guidances. |  | |  | |  |
| Provision of certificate of Batch Confirmation of the partial manufacture of <specified outsourced step(s) of manufacture> |  | |  | |  |
| Review and confirm all aspects regarding the steps of manufacture and control of the batch on the certifying site of manufacture, according to the Marketing Authorisation and:   * Certificates of Batch Confirmation are provided by APs from all the sites involved in outsourced steps of manufacture and testing * manufacturing steps performed are consistent with, the requirements of Market Authorisation (ARTG) and compliant with cGMP * ongoing stability data is current and consistent with the MA and the PQR is current |  | |  | |  |
| Provision of a Batch Certification on letter head of the certifying manufacturer consistent with PIC/S PE-009 Guide Annex 16 requirements and signed by the certifying AP  Note: this may be combined with the Certificate of Analysis |  | |  | |  |
| **STORAGE AND TRANSPORT:** | | | | | |
| Maintenance of a Wholesale / Poisons License or any other authorisation or entitlement by local authorisations to procure, hold, supply products and export products |  | |  | |  |
| Storage of product consistent with storage specifications in the control of the Contract Acceptor |  | |  | |  |
| Provision of details of appropriately licensed warehouse/wholesaler for receipt of goods |  | |  | |  |
| Determination of specific transport requirements (refrigerated, dangerous goods, or other) |  | |  | |  |
| Provision of transport to meet requirements (refrigerated, dangerous goods, or other) |  | |  | |  |
| Communication of transport verification, including review of temperature monitoring data, investigation of temperature excursions and reporting for the awareness of the sponsor and the certifying AP |  | |  | |  |
| Request for shipment of any stock under quarantine must be made in writing, with confirmation the recipient warehouse holds a GMP licence for storage of quarantined product |  | |  | |  |
| Approval/Authorisation of shipment under quarantine |  | |  | |  |
| Movement of stock under quarantine must be clearly marked with status before dispatch |  | |  | |  |
| Verification that transport/shipping is conducted consistent with specifications |  | |  | |  |
| **PRODUCT STABILITY:** | | | | | |
| Provision of product shelf life and supporting evidence - stability summary or technical justification where the medicine is listed |  | |  | |  |
| Acceptance of evidence/justification for shelf life |  | |  | |  |
| Provision of ongoing stability program and the results to the certifying AP. |  | |  | |  |
| Generation of Stability Protocol |  | |  | |  |
| Approval of Stability Protocol |  | |  | |  |
| Authorisation of Stability Protocol |  | |  | |  |
| Preparation and maintenance of stability indicating analytical methods |  | |  | |  |
| Authorisation of stability indicating analytical methods |  | |  | |  |
| Validation of analytical stability indicating method(s) |  | |  | |  |
| The management and final determination of Stability OOS or OOT results to be communicated to the certifying AP |  | |  | |  |
| [**QUALITY ISSUES**](#_Glossary_of_terms) **(INCLUDING** [**DEVIATIONS**](#_Glossary_of_terms)**,** [**NCP**](#_Glossary_of_terms)**,** [**CAPA**](#_Glossary_of_terms)**,** [**OOS**](#_Glossary_of_terms)**,** [**OOT**](#_Glossary_of_terms)**)**  *(For this section it is acceptable to have multiple manufacturers to be nominated for raising of these quality issues as relevant to their steps of manufacture)* | | | | | |
| Preparation of the relevant quality issue form including the categorisation into a critical or non-critical issue as applicable. |  | |  | |  |
| Notification of the Contract Giver of the quality event that may impact the product quality or the Marketing Authorisation in writing within <an agree time frame>. |  | |  | |  |
| Investigation of the quality issue(s) |  | |  | |  |
| Preparation and provision of the Investigation report on the incident, unplanned deviation, NCP, CAPA OOS or OOT, including root cause analysis to the Contract Giver |  | |  | |  |
| Approval of the report on the quality issues/raised by Contract Acceptor/s |  | |  | |  |
| Authorisation of the report on the quality issues raised by the Contract Acceptor/s and advice of the Contract Giver’s determined course of action |  | |  | |  |
| Prior notification to Contract Giver of a proposed deviation from approved Manufacturing Batch Processing Instruction or Packaging Instruction, where impacting on product quality or the Marketing Authorisation |  | |  | |  |
| Prior notification to Contract Giver of a proposed deviation from approved Manufacturing Batch Processing Instruction or Packaging Instruction, where not impacting on product quality or the Marketing Authorisation |  | |  | |  |
| Approval of proposed deviation |  | |  | |  |
| Authorisation of proposed deviation |  | |  | |  |
| Review of deviation outcomes and preparation of report |  | |  | |  |
| Provision of report to Contract Giver |  | |  | |  |
| Authorisation of report and corrective and preventative actions and future recommendations |  | |  | |  |
| **CHANGE CONTROL/MANAGEMENT** | | | | | |
| Notification of changes impacting product quality or Marketing Authorisation to the Contract Giver |  | |  | |  |
| Approval of changes impacting product quality or the Marketing Authorisation to the Contract Giver |  | |  | |  |
| Notification of changes impacting product quality or Marketing Authorisation to the Contract Acceptor |  | |  | |  |
| Authorisation of changes impacting product quality or the Marketing Authorisation to the Contract Acceptor |  | |  | |  |
| Preparation of Change Control documentation including the classification/categorisation of the type of change and identifying steps necessary and timing to implement and confirm the change |  | |  | |  |
| Approval of the Change Control documentation |  | |  | |  |
| Authorisation of the Change Control |  | |  | |  |
| Application for approval for all changes to the Marketing Authorisation prior to implementation requirement (where necessary) |  | |  | |  |
| Implementation of Change Control steps |  | |  | |  |
| Review of Change Control, confirming completion of implementation and confirmation the intent of the change was effective |  | |  | |  |
| Authorisation of closure of the Change Control |  | |  | |  |
| **REWORK**/[**RECOVERY/REPROCESSING**](#_Glossary_of_terms)**:** *(Unless pre-agreed in writing by Contract Giver reworking of intermediate bulk or finished product is not permitted)*  *)* | | | | | |
| Preparation of a proposal for rework or reprocessing including controls/need for stability data |  | |  | |  |
| Approval/Refusal of rework or reprocessing proposal |  | |  | |  |
| Preparation of rework or reprocessing instructions |  | |  | |  |
| Approval of rework or reprocessing instructions |  | |  | |  |
| Authorisation of rework or reprocessing documentation for use |  | |  | |  |
| Implementation of rework or reprocessing as per approved instructions |  | |  | |  |
| Inclusion of rework or reprocessing details in the product quality review |  | |  | |  |
| **COMPLAINT INVESTIGATION** | | | | | |
| Obtain complaint sample(s), review and documentation and trending of all complaints received with regards the product |  | |  | |  |
| Investigation of complaints relating to product design |  | |  | |  |
| Investigation of complaints relating to manufacture of dosage form |  | |  | |  |
| Investigation of complaints relating to packaging of product |  | |  | |  |
| Provision of or access to relevant batch documentation to support complaint investigation |  | |  | |  |
| **RECALL PROCEDURE:** | | | | | |
| Organisation and instigation of mock recall |  | |  | |  |
| Provision of manufacturing documentation to support mock recall |  | |  | |  |
| Provision of packaging documentation to support mock recall |  | |  | |  |
| Provision of laboratory data to support mock recall |  | |  | |  |
| Notification of the possible need to recall due to a manufacturing issue |  | |  | |  |
| Notification of the possible need to recall due to a product authorisation issue |  | |  | |  |
| Notification to the National Regulatory Agency and management of the Recall |  | |  | |  |
| Management of stock recalled from the market. |  | |  | |  |
| Destruction of stock recalled from the market. |  | |  | |  |
| **PHARMACOVIGILANCE INVESTIGATION & REPORTING (consider whether a separate PV agreement is necessary)** | | | | | |
| Pharmacovigilance reporting to regulator including:   * Submission of serious adverse reactions * Notification of significant safety issues identified * Notification of quality defect issues, adulterated product or counterfeit products * Maintaining all records serious and non-serious for the life of the product and for:   + a period of 10 years after removal from the ARTG for registered medicines, and   + a period of 5 years after removal from the ARTG for listed medicines |  | |  | |  |
| Monitoring for serious adverse reactions associated with the use of the stated medicine(s), occurring in Australia or reported in published international scientific literature, validating all serious adverse reactions and maintaining records of adverse reactions |  | |  | |  |
| Provision of relevant records to support investigation or inspection, as requested by the regulator, to meet the relevant reporting or regulator requested timeframe |  | |  | |  |
| Provision of access to the site, as necessary for a Pharmacovigilance Inspection conducted by the regulator |  | |  | |  |
| Preparation of CAPA plan that appropriately addresses the non-compliance identified at an inspection is completed and submitted |  | |  | |  |
| Provision of support in preparation of the CAPA plan as necessary |  | |  | |  |
| Implementation of agreed actions by the contract acceptor and provision of objective evidence |  | |  | |  |
| Submission of the compiled objective evidence to the Regulator to close out the CAPA by the Contract Giver. |  | |  | |  |
| **OUTSOURCED ACTIVITIES** | | | | | |
| Notification of any outsourced activities, for example:   * QC Laboratory Testing, * Stability Testing. * Cleaning, * Calibration / maintenance * Uniforms supply, * Waste disposal. * Packaging activities * Warehousing * Pharmacovigilance * Irradiation |  | |  | |  |
| Approval for the contract acceptor to sub-contract to a third party any of the work entrusted under this agreement |  | |  | |  |
| Confirmation of appropriate licensing/certification of the contract acceptor |  | |  | |  |
| Confirmation written commercial contracts are in place and GMP agreements where appropriate |  | |  | |  |
| Qualification of contracted manufacturers that conduct a step in the bulk manufacture of the medicine (including licensing and or certifications) |  | |  | |  |
| Qualification of contracted manufacturers that conduct a packaging step (including licensing and or certifications) |  | |  | |  |
| Qualification of contracted laboratories that conduct analytical testing (including licensing and or certifications) |  | |  | |  |
| Qualification of contracted warehousing (including licensing and or certifications) |  | |  | |  |
| Qualification of contracted transport where temperature control is necessary |  | |  | |  |
| Oversight and inspection of outsourced activity providers |  | |  | |  |
| Handling and secure disposal of waste arising from manufacture of the products (including samples, printed packaging components and rejected semi-finished or finished product) to be carried out in accordance with documented methods compliant with relevant Environmental and Health & Safety legislation |  | |  | |  |
| Maintenance of a manifest of securely disposed items |  | |  | |  |
| Approval of outsourced providers and update to  Appendix 1 |  | |  | |  |
| Notification of any change to outsource provider |  | |  | |  |
| **GMP COMPLIANCE SIGNALS** | | | | | |
| Notification to the Contract Giver of Critical or Major deficiencies identified by Inspection Agencies relating to any manufacturers involved in the supply chain within <an agreed timeframe> |  | |  | |  |
| Investigation of the deficiencies identified to determine impact on product compliance subject to this agreement |  | |  | |  |
| Risk assessment and identification of any batches impacted |  | |  | |  |
| Provision of Risk Assessment Report to the Contract Giver |  | |  | |  |
| Notification of regulatory compliance (APIs) |  | |  | |  |
| Notification to National Regulatory Agency/Agencies |  | |  | |  |
| Provision of records of traceability of all units of each batch manufactured stored and distributed as necessary |  | |  | |  |
| **PRODUCT QUALITY REVIEWS – Regular periodic or rolling quality reviews of all products subject to the agreement.** | | | | | |
| Provision of review all quality-related returns, complaints and recalls and the investigations performed at the time |  | |  | |  |
| Provision of review of post marketing commitments to new marketing authorisations and variations to marketing authorisations |  | |  | |  |
| Provision of review the Marketing Authorisation variations submitted/granted/refused, including those for third country (export only) supply |  | |  | |  |
| Provision of review starting materials used in bulk manufacture and packaging processes |  | |  | |  |
| Provision of review of critical in-process controls in manufacture and finished product results |  | |  | |  |
| Provision of review of all bulk batches that fail to meet established specifications and their investigation |  | |  | |  |
| Provision of review of all packed batches that fail to meet established specifications and their investigation |  | |  | |  |
| Provision of review all significant deviations or non-conformances, Non-conformances and CAPA’s, their related investigations, and the effectiveness of resultant corrective and preventative actions taken regarding manufacture |  | |  | |  |
| Provision of review all significant deviations or non-conformances, their related investigations, and the effectiveness of resultant corrective and preventative actions taken regarding testing |  | |  | |  |
| Provision of review of all changes carried out to the bulk manufacturing processes |  | |  | |  |
| Provision of review of all changes carried out to the processes involved in the packing activity |  | |  | |  |
| Provision of review of all changes carried out to analytical (and other testing) methods |  | |  | |  |
| Provision of review of analytical method validations / justifications |  | |  | |  |
| Provision of review the results of the stability of the bulk product and any adverse trends |  | |  | |  |
| Provision of review the results of the stability of the marketed product monitoring program and any adverse trends |  | |  | |  |
| Provision of review the adequacy of any previous product process or equipment corrective actions relating to manufacture of the product |  | |  | |  |
| Provision of review of qualification status of relevant equipment and utilities used in the manufacture |  | |  | |  |
| Provision of review any contractual arrangements relating to the manufacture of the product as defined in Chapter 7 (of the code) to ensure that they are up to date |  | |  | |  |
| Collation and evaluation of the Product Quality Review to determine the need for Corrective and Preventive Action or revalidation should be undertaken |  | |  | |  |
| Preparation of Final Summary of Product Quality Review(s) |  | |  | |  |
| Authorisation of Final Product Quality Review(s) |  | |  | |  |
| Provision of complete report of Product Quality Review(s) to Authorised person |  | |  | |  |
| Provision of a copy of the report to the Contract Giver |  | |  | |  |
| **OTHER GMP RESPONSIBILITIES:** | | | | | |
| Retain distribution traceability records |  | |  | |  |
| Retain and make accessible as necessary all completed PQS-related documentation or records (paper or electronic) in a secure location for a minimum period of 7 years, or expiry of product plus 2 years or Contract Acceptor’s retention policy (whichever is longer); in such a manner as to maintain their traceability and integrity throughout the required retention period (**Note**: validation and records/data to support the product claims must be kept for the life of the product) |  | |  | |  |
| Provision of site access for audit by the Contract Giver with prior notice at a date/time acceptable to both parties |  | |  | |  |
| Provision of a traceability system to ensure identification of the product (lot codes, expiry dates etc), control of the release of the product and stock rotation according to first expiry, first out (FEFO) |  | |  | |  |
| Immediate notification of the Certifying AP when any communication from a regulator concerning the quality or regulatory status of a product or the status of a site involved the manufacture of a product subject to the agreement |  | |  | |  |
| Notification of Contract Giver of any changes to the scope of the manufacturer’s licence |  | |  | |  |

# Glossary of terms

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| --- | --- |
| Term | Meaning |
| Approval | Approval is the term used to reference the action of the Contract Giver’s review and approval of a document or report, particularly with respect to its consistency with the Marketing Authorisation details. |
| Authorisation | Authorisation is the term used to reference the action of the Contract Acceptor’s authorisation for release of a controlled document for its use within the PQS (QMS) and its consistency with cGMP. |
| CAPA - Corrective And Preventative Action | A report identifying the appropriate corrective actions and/or preventive actions (CAPAs) necessary in response to investigations into a quality issue, incident or finding, with the aim that PQS is strengthened such that the same situation should not occur again. The effectiveness of such actions should be monitored and assessed, in line with Quality Risk Management principles; (PIC/S Ch 1.4 (xiv), 8.9 (ix), Ch 8.18) |
| Contract Giver | In this template, the term Contract Giver is used to reference the [Sponsor](#_Glossary_of_terms) (the Marketing Authorisation Holder).  However, in some GMP agreements it may not always be the case. For example, the Contract Giver may be a manufacturer who outsources a step of manufacture to another party, e.g. to a laboratory for analytical testing, or to another manufacturer with specialised packaging capability.  (PIC/S Part I Ch 7) |
| Contract Acceptor | Typically, the Manufacturer(s) and/or other outsource providers for steps of manufacture. There can be more than one contract acceptor included in the agreement. |
| Deviation | Departure from an approved instruction or established standard. (PIC/S Part II Glossary) |
| Functional Packaging | Non-printed packaging, including primary secondary or tertiary packaging which has a functional purpose:   * primary packaging, e.g. bottles, tubes. PVC/PVdC blister, * secondary/tertiary packaging e.g. cardboard outers/shippers. |
| Marketing Authorisation | The Australian Register of Therapeutic Goods (ARTG) entry of the product |
| NCP - Non-conforming Product | Is product that does not fulfill its specified requirements |
| OOS – Out of Specification | Results of a test which fall outside the numerical limits, ranges, or other criteria for the test described are called out of specification. This means the material or product has not met its established set of criteria and is not considered acceptable for its intended use. Results out of specification should be investigated. |
| OOT – Out of Trend | Once a statistically significant number of batches of a starting material or intermediate or finished dosage form have been tested, the data lends itself to allow for trend analysis.This provides for a narrower trend range of expected results within the Specification.  Results outside of the trend range are known as OOT and should be investigated.  (PIC/S Part I 6.32) |
| Packaging material | Any material employed in the packaging of a medicinal products, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.  (PIC/S PE009-16 Glossary after the Annexes) |
| PQS - Pharmaceutical Quality System | Formerly called the Quality Management System (QMS) is the sum total of the organised arrangements (systems, processes, procedures) established by the manufacturer with the objective of ensuring that medicinal products are of the quality required for their intended use. Quality Management therefore incorporates Good Manufacturing Practice, Quality Assurance and Quality Control. |
| Printed Packaging | All printed packaging, e.g. labels, cartons, blister foil, shrink seals, tamper evident seals, printed tubes. |
| Quality Issue | All quality incidents arising from faulty manufacture, product deterioration, detection of falsification, non-compliance with the Marketing Authorisation or product specification file, or any other serious quality problems.   * requiring timely and effective communication and escalation process exists to raise quality issues to the appropriate levels of management.   contact those responsible at each party for the management of quality defect and recall issues. (PIC/S Guide PE009-16 Ch 2.9(xiii) and Ch 8 Principle) |
| Recovery | The introduction of all or part of previous batch(es) of the required quality into another batch at a defined stage of manufacture.  (PIC/S PE009-16 Glossary after the Annexes) |
| Reprocessing | The reworking of all or part of a batch of product of an unacceptable quality from a defined stage of production, so that its quality may be rendered acceptable by one or more additional operations.  (PIC/S PE009-16 Glossary after the Annexes) |
| Specification | A list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the test described. It establishes the set of criteria to which a material should conform to be considered acceptable for its intended use. “Conformance to specification” means that the material, when tested according to the listed analytical procedures, will meet the listed acceptance criteria.  (PIC/S PE009-16 Glossary after the Annexes) |
| Sponsor | in relation to therapeutic goods, means:  (a) a person who exports, or arranges the exportation of, the goods from Australia; or  (b) a person who imports, or arranges the importation of, the goods into Australia; or  (c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);  (Therapeutic Goods Act, 1989) |
| Starting material | Any substance used in the production of a medicinal products but excluding packaging materials.  (PIC/S PE009-16 Glossary after the Annexes) |
| Step(s) of manufacture | The steps of manufacture for medicines supplied in Australia are listed and defined under the Code Tables for Manufacturing Steps and manufacturing Steps Group accessed via [https://www.ebs.tga.gov.au/](https://www/.ebs.tga.gov.au/)  These coded steps of manufacture (and groups of those steps) are used to describe the steps that a manufacturer is licensed to undertake relative to dosage forms, as well as the steps of manufacture required to be recorded in the Marketing Authorisation. The required coded steps of manufacture for different types of medicines (e.g. prescription, registered non-prescription and listed medicines) are detailed both within the application form for that medicine type and are also detailed in the [GMP clearance code tables guidance](https://www.tga.gov.au/resource/gmp-clearance-code-tables-guidance). e.g. API premix, manufacture of dosage form, packaging and labelling, secondary packaging, testing chemical and physical, testing microbial and batch certification. See the following steps of manufacture as an example.   |  | | --- | | Steps of manufacturing:   * API non sterile – includes all steps in the manufacture (e.g. for herbals – extraction, drying, milling, mixing, spray drying) packaging/labelling, chemical/physical testing | | * API- Active Premix – blending or mixing the API with one or more excipients | | * Testing - Chemical and Physical | | * Testing - Microbiological | | * Manufacture of dosage form – includes all steps of manufacture (e.g. for tablets - dispensing, granulating, drying, blending, compressing, coating) | | * Packaging and Labelling | | * Secondary Packaging | | * Release for Supply/Batch Certification | | * Storage | | * Transportation | | * Distribution Warehousing | |

# Approved Subcontractors

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| --- | --- | --- | --- |
| Subcontractor | Address | Manufacturing Step | TGA Licence/GMP Clearance |
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| --- | --- | --- | --- |
| Authorised on  behalf of | Contract Giver | Contract Acceptor 1 | Contract Acceptor 2 |
| Name: |  |  |  |
| Title: |  |  |  |
| Signature: |  |  |  |
| Date: |  |  |  |

# Key Contacts for each of the parties

Contract Giver

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title | Name | Contact Details | Signature | Date |
| QA Manager |  | Email:  Tel:  Mobile: |  |  |
| Regulatory Manager |  | Email:  Tel:  Mobile: |  |  |
|  |  |  |  |  |

Contract Acceptor 1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title | Name | Contact Details | Signature | Date |
| QA Manager |  | Email:  Tel:  Mobile: |  |  |
| Authorised/Qualified Person(s) |  | Email:  Tel:  Mobile: |  |  |
| QC Manager |  | Email:  Tel:  Mobile: |  |  |
| Regulatory Manager |  | Email:  Tel:  Mobile: |  |  |
| Production Manager |  | Email:  Tel:  Mobile: |  |  |

**Contract Acceptor 2**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title | Name | Contact Details | Signature | Date |
| QA Manager |  | Email:  Tel:  Mobile: |  |  |
| Authorised/Qualified Person(s) |  | Email:  Tel:  Mobile: |  |  |
| QC Manager |  | Email:  Tel:  Mobile: |  |  |
| Regulatory Manager |  | Email:  Tel:  Mobile: |  |  |
| Production Manager |  | Email:  Tel:  Mobile: |  |  |
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| --- | --- | --- | --- |
| Authorised on  behalf of | Contract Giver | Contract Acceptor 1 | Contract Acceptor 2 |
| Name: |  |  |  |
| Title: |  |  |  |
| Signature: |  |  |  |
| Date: |  |  |  |

# Products Subject to the Agreement

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| --- | --- | --- | --- | --- |
| Product Code | Product Name | ARTG No.  (or “TBA”) | Specification Reference | Storage/ Transport Conditions |
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| Authorised on  behalf of | Contract Giver | Contract Acceptor 1 | Contract Acceptor 2 |
| Name: |  |  |  |
| Title: |  |  |  |
| Signature: |  |  |  |
| Date: |  |  |  |

# Document History

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| --- | --- |
| Date of Issue | Reason(s) for Change |
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| --- | --- | --- | --- |
| Authorised on  behalf of | Contract Giver | Contract Acceptor 1 | Contract Acceptor 2 |
| Name: |  |  |  |
| Title: |  |  |  |
| Signature: |  |  |  |
| Date: |  |  |  |

# Annex 1. Steps of Manufacture by site for each product

|  |  |
| --- | --- |
| Product Name |  |
| ARTG No. |  |

<see Steps of Manufacturing entry in [glossary of terms](#_Glossary_of_terms)>

|  | Manufacturer | Manufacturer Address | Steps of Manufacture | TGA licence/  GMP Clearance  (ISO 17025 for Laboratory if applicable) |
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| ACTIVE |  |  |  |  |
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| ACTIVE PREMIX |  |  |  |  |
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| SUPPLIER/LOCAL AGENT |  |  |  |  |
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| FINISHED PRODUCT |  |  |  |  |
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| TRANSPORT AND STORAGE |  |  |  |  |
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| --- | --- | --- | --- |
| Authorised on  behalf of | Contract Giver | Contract Acceptor 1  (where the detail of some parties involved is confidential, the contract giver may choose to include the certifying AP as the only other signatory. ) | Contract Acceptor 2 |
| Name: |  |  |  |
| Title: |  |  |  |
| Signature: |  |  |  |
| Date: |  |  |  |