Quality Assurance Agreement
(Ref. SOP QMS-015)

TEM-100

Issue Date:

COMPANY NAME AND LOGO
GMP-XXX.Y.Z (See **QMS-015** for numbering system)

QUALITY ASSURANCE AGREEMENT

Between

(1) BUYER

(2) Contractor XXX

FOR PRODUCTS
(Write the product/s name)

SIGNED

Quality Assurance Dept. **On behalf of [site name]**	é é é é é é é é é é . **Quality Assurance Manager**	é é é é é é é . **Date**
Quality Assurance Dept. **On behalf of Contractor**	é é é é é é é é é é é é é **(Person's name)** **(Positions)**	é é é é .é é é **Date**

Review Date: 4 years from last signature date

2.5.4. BUYER is responsible for ensuring this document is updated. This document shall be revision controlled. PROCESSOR shall notify BUYER of any potential changes that may impact on this agreement prior to implementation.

2.5.5. BUYER is responsible for the transfer of technology to enable PROCESSOR to undertake the processing, analysis, packing, release and distribution.

3. ARTICLE 3 – PROCESSING, ANALYSIS, PACKING AND RELEASE

3.1. PROCESSOR shall ensure that the processing, analysis and/or packing, and analysis of PRODUCTS are in compliance with the items specified in Article 1.2, applicable to the markets that will be supplied with product.

3.2. PROCESSOR and BUYER shall agree who is responsible for the Quality Management of the suppliers of starting and/or packaging materials appropriate to the stage of manufacture that PROCESSOR is undertaking.

3.3. PROCESSOR's facilities together with any other peripheral services shall be subject to audit and/or inspection by BUYER upon reasonable notice. PROCESSOR shall permit BUYER to visit and observe **processing, analysis, packing, release and/or distribution** of PRODUCTS upon reasonable notice.

3.4. The proposed use of a sub-contractor by PROCESSOR shall be notified to BUYER and approved in writing, prior to implementation. PROCESSOR shall perform periodic audits of their sub-contractors of manufacturing, laboratories, warehouses and any other peripheral services that are used in connection with the supply of PRODUCTS to BUYER.

3.5. PROCESSOR shall inform BUYER Quality Assurance Contacts by the next working day of becoming aware of quality issues, including significant deviations, which might compromise PRODUCTS already shipped to BUYER. BUYER shall not release such PRODUCTS until PROCESSOR and BUYER have determined, in writing, that such issues are consistent with cGMP and/or registered detail requirements. BUYER is responsible for the final disposition of PRODUCTS.

3.6. PROCESSOR shall maintain local change control systems that assure that only changes, which comply with cGMPs, and Registered Detail Requirements, are authorised and implemented. Where PROCESSOR is considering changes that potentially impact on the Registered Detail Requirements, PROCESSOR shall notify BUYER. BUYER will obtain internal BUYER approval and Regulatory Authority approval, where necessary, prior to implementation by PROCESSOR.

3.7. PROCESSOR is responsible for performing and documenting validation of equipment, facilities, processes, computers and cleaning in accordance with cGMPs and the Technology Transfer Package.

3.8. BUYER and PROCESSOR shall agree which validation plans, protocols and reports BUYER, shall approve, and the process for the approval of validation for approved changes.

3.9. PROCESSOR is responsible for performing and documenting the establishment of analytical methods, qualification of equipment and facilities, and validation of processes, equipment cleaning and computer applications.

3.10. BUYER is responsible for providing the approved pack text for **labels, leaflets, cartons, pack inserts, etc**. to PROCESSOR where PROCESSOR is conducting packing on behalf of the BUYER.

CONTACTS LIST **APPENDIX 1**

	BUYER	PROCESSOR
DETAILS OF CONTACTS	**Quality Assurance Dept.**	
CONTACT NAME		
CONTACT TITLE	**Quality Assurance Manager**	
ADDRESS (if different than that specified on page 3)		
PHONE NUMBER		
FAX NUMBER		
DETAILS OF DELEGATION		
ADDRESS OF DELEGATION (If different)		
DEPUTY'S CONTACT TITLE		
DEPUTY'S PHONE NUMBER		
DEPUTY'S FAX NUMBER		

LIST OF SUPPLY/TOLL AGREEMENTS

APPENDIX 4

(Describe the agreed transportation system used for product shipment)

Quality Assurance Agreement

(Ref. SOP QMS-015)

LIST OF SIGNIFICANT QUALITY EVENTS — APPENDIX 10

Any Product quality event determined by Supplier to result in a deviation or require a failure investigation and to impact Product quality is a Significant Quality Event, including each of the following events, (if such event is significant enough to require a deviation or failure investigation):

- Rejection of a batch or lot.
- Out of specification (OOS) investigation (quarantine or rejection of a batch or any part of a batch or lot due to failure to meet established release specification or in-process specifications established in the applicable Product Requirements).
- Stability failure or significant change in adverse trend compared to expected results.
- Product, packaging or labeling mix-up involving the batch or lot.
- Probable or known cross contamination of a Product with another product, extraneous foreign material or microorganisms.
- In-process or finished Product testing trends that indicate that a batch/lot performs outside the established [process capability limits or alert limits] or [action or alert limits].
- Batches subject to rework or reprocessing where not registered.
- Batches associated with an equipment malfunction where registered process parameters are impacted.
- Batches subject to a [major] malfunction of a facility utility system.
- Batches subject to natural disasters such as flooding, fire, earthquake, lightning strike.
- Batches requiring a formal investigation for the following: reconciliation discrepancy; line clearance failure, sterility failure, environmental monitoring failure or alert
- Bulk or packaged lots which exceeded the established Product Hold Times in bulk containers.
- [In-process or finished] Product stored outside the established environmental conditions.
- Deviations from established time limits for the completion of production step.