DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Technical Agreement	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1. **Purpose:** The purpose of this SOP (Standard Operating Procedure) is to describe the procedure for preparation and handling of all technical agreements.

2. **Scope:** This procedure applies to handling of all technical agreements at ……

3. **References & Annexures:**
   - 3.1. **References:**
     - 3.1.1. In house
     - 3.1.2. WHO TRS: 961
   - 3.2. **Annexures:** NA
4. **Responsibilities:**
   - 4.1. **Quality Assurance (QA) :**
     - 4.1.1. To prepare list of document of Technical Agreements and retain one copy of such document.
     - 4.1.2. To review the list periodically and ensure that all agreement getting due are reviewed and revised.
     - 4.1.3. To review and revise the SOP (as and when required)
     - 4.1.4. To ensure implementation of SOP.
   - 4.2. **User Department:**
     - 4.2.1. To prepare and revise the agreement as per SOP.
     - 4.2.2. To evaluate or audit the external party before signing any agreement.
     - 4.2.3. To intimate and provide the copy of technical agreement to QA for review and retention purpose.
     - 4.2.4. To review and renew the agreement before they are getting due.
   - 4.3. **User Department Head:**
     - 4.3.1. To review and approve the SOP.
     - 4.3.2. To ensure implementation of the SOP.
   - 4.4. **Regulatory Affairs, Quality Head and Plant Head :**
     - 4.4.1. To review and approve the SOP.

5. **Distribution:**
   - 5.1. QA

6. **Abbreviations and Definition of Terms :**
   - 6.1. **Abbreviations :**
     - 6.1.1. SOP: Standard Operating Procedure
     - 6.1.2. QA: Quality Assurance
     - 6.1.3. CC No.: Change Control number
     - 6.1.4. NA: Not Applicable
     - 6.1.5. CQ : Corporate Quality.
   - 6.2. **Definition of Terms :**

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6.2.1. **Agreement:** Agreement undertaken by written and legally binding on two parties (Contract giver and contract acceptor).

6.2.2. **Contract:** Business agreements between two parties for supply of goods and performance of work at a specific price for a specific time period.

7. Procedure:

7.1. QA shall ensure that for all technical services or any other services which has co-relation with GMP activity and are availed from a outside agency, shall be through a formal agreement which clearly defines the role and responsibilities of both the parties.

7.2. Contract analysis must be correctly defined, agreed and controlled in order to avoid any misunderstanding, by defining the responsibilities and communication processes for quality related activities of the parties concerned.

7.3. The contract should permit the contract giver to audit the facilities of the contract acceptor.

7.4. The contract giver shall be responsible for assessing the competence of the contract acceptor by successfully carrying out the work or tests required, for approval of contract activities or any other legal requirements.

7.5. The contract giver shall be responsible for monitoring and review of the performance of the contract acceptor or the quality of the material from the provider, and identification and implementation of any improvements needed.

7.6. The contract acceptor must have adequate premises, equipment, analytical instrument, knowledge, and experience of competent personnel to carry out satisfactorily the work ordered by the contract giver.

7.7. Each technical agreement shall contain clearly defined scope of agreement, role & responsibility of both the parties, time period for which the agreement shall be effective and conditions in which the agreement shall cease automatically or terminated by any of the party.

7.8. All Technical agreements shall be prepared by the user department and representative of service provider and shall be signed by the appropriate authority from both the parties. QA may or may not be the signing authority but shall be over all controlling authority for all GMP related issues.

7.9. If required, such agreement can be prepared on appropriate stamp papers. Approval by legal department shall be taken, if required.

7.10. The contract giver should ensure that the contract acceptor is fully aware of any problems associated with the product, work or tests that might pose a hazard to premises, equipment, personnel, other materials or other products.

7.11. The contract giver should provide the contract acceptor with all necessary information to enable compliance with expectations regarding services or goods. This assures that the work or service is performed in compliance with existing regulations.

7.12. The contract acceptor should not pass to a third party any of the work entrusted to him or her under the contract without the contract giver's prior evaluation and approval of the arrangements. Arrangements made between the contract acceptor and any third party should ensure that the testing and analytical information is made available in the same way as between the original contract giver and contract acceptor.

7.13. The contract acceptor should refrain from any activity that may adversely affect the quality of the product manufactured and/ or analyzed for the contract giver.

7.14. For providing technical services vendor shall be selected based on overall evaluation of party and only competent parties shall be assigned with such responsibilities.

7.15. **The contract:**

7.15.1. There must be a written contract between the contract giver and the Contract acceptor which clearly establishes the responsibilities.

7.15.2. Technical aspects of the contract should be drawn up by competent persons suitably knowledgeable in pharmaceutical technology, analysis and GMP.

7.15.3. All arrangements for analysis and calibration/ validation must be in accordance with the marketing authorization and agreed by both parties.

7.15.4. Technical agreement shall not bear the commercial terms. However if included, those terms shall not be binding from GMP prospective.

7.16. QA shall prepare a list of such technical document for review and signed on the agreement copy and also retain copy of such document.

7.17. Following are the services, but not limited to, for which agreement should be available if the services are received from an outside agency.

7.17.1. Agreement for HVAC qualification

7.17.2. Agreement for Compressed air testing

7.17.3. Agreement of Operation and maintaining the quality of treated effluent water and assistance for pollution control related matter.

7.17.4. Agreement for Water storage tank cleaning.

7.17.5. Agreement for Medical checkup.

7.17.6. Contract for Pest and Rodent control

7.17.7. Agreement for maintaining Fire Extinguisher cylinder.

7.17.8. Agreement for Supplying labor on contract basis.

7.17.9. Agreement for Vigilance services/security.

7.17.10. Agreement between SPLL and service Provider Company/agency for servicing and calibration of Equipment and Instruments.

7.17.11. Agreement with Medical Practitioner for providing Medical facility.

7.17.12. Agreement for Contract analysis (Both internal and External).

7.17.13. Agreement with Transporters and Courier agencies.

7.18. QA shall review the list periodically and ensure that all agreements getting due are reviewed and revised.

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7.19. **Following format can be used for preparation of Technical Agreement.**

Company Name & Address

AGREEMENT FOR …. (TITLE)……

Contract Giver:
Decodingpharma
P.O. ……..
Tel. No.
Fax No.

Contract Acceptor:
Detail address of contract acceptor

Note: This format can be customized, if required.

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8. History:

Revision No	Effective Date	Revision Details	CC No
00		NA	NA

New SOP