

# POLICY ON QUALITY AGREEMENT MANAGEMENT

## INTRODUCTION:

This document provides the policy for Quality Technical Agreement to assure compliance with applicable current Good Manufacturing Practices (cGMP)

## SCOPE:

This policy is applicable for all outsourced cGMP activities carried out on contractual arrangements between ..... and Customer/Supplier for commercial sale and /or distribution of final end product.

All GMP and GDP requirements of ..... that are outsourced with Customer/Supplier or as Intracompany require that responsibilities and obligations of each of the entities are agreed in the form of a QTA.

## POLICY DETAILS:

There shall be a Quality Technical Agreement between ..... and Customer/ Supplier for all outsourced cGMP activities.

There shall be a written procedure in place for management of Quality Technical Agreement. Quality Technical Agreement at the minimum shall contain the following basic sections:

- Parties to the agreement:
- Purpose/ Scope
- Definitions: Terms and Terminations
- Products/material /services
- Communication mechanism and key Quality contacts
- Outline of quality responsibilities
- Confidentiality:
- Approval signatures

- ✧ Quality Technical Agreement shall be a separate document from Commercial contracts.
- ✧ The Quality Technical Agreements shall be in place prior to Commercial distribution /sale, usage of material / GMP services.
- ✧ The Quality Technical Agreement shall be approved and signed by authorized personnel of the parties involved in Quality Technical Agreement.
- ✧ The Quality Technical Agreement shall be reviewed as per defined frequency and/or whenever there are any changes in terms and conditions.
- ✧ Any changes in the Quality Technical agreements shall be recorded in the Change history. Quality Technical Agreement shall be retained by both the parties.

## AMENDMENT AND WAIVER:

The company reserves the right to amend, alter and/or terminate this policy at any time.

## DEFINITION:

Customer: The company or organisation receiving the product e.g. Raw materials , packaging materials , finished product once it has left the control of the manufacturers; includes users and distributors.

Quality Technical Agreement: A legally binding agreement that is mutually negotiated and concluded between the Quality Departments of manufacturers and their customers. It is intended to define, in a formalised manner, responsibilities relative to quality tasks to assure the manufacture, supply and use of safe materials

# POLICY ON QUALITY AGREEMENT MANAGEMENT

acceptable for pharmaceutical use, GMP services.

## ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practise
GDP	:	Good Distribution Practices
QTA	:	Quality Technical Agreement
USFDA	:	United States Food and Drug Administration

## REFERENCES:

USFDA guidelines on "Contract manufacturing arrangement for drugs: "Quality Agreements" EUDRALEX Volume 4 Chapter 7