

# POLICY ON CONSULTANTS

## INTRODUCTION:

..... understands that consultants are required to provide advice on various technical aspect. Consultants should be having high proficiency and knowledge in the respective subject.

## SCOPE:

This policy is applicable to appointment and management of consultants / consultancy firms in ..... and its associated units.

## POLICY DETAILS:

They shall be appointed to strengthen the competencies identified by the Management.

The scope of consultants/consultancy shall be limited to identified areas only.

There shall be an agreement in place before execution of activity.

Consultants shall ensure that confidentiality of the data is maintained during and post the activity.

Consultants/consultancy shall be selected based on predefined criteria, including but not limited to reputation, experience, training abilities and proven track record.

Wherever applicable, consultants/consultancy approved by regulatory agencies shall be employed. Records shall be maintained stating details of consultants/consulting firms and type of service provided.

## AMENDMENT AND WAIVER:

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

## DEFINITION:

Not Applicable

## ABBREVIATIONS:

API : Active Pharmaceutical Ingredient

CFR : Code of Federal Regulations

EU : European Union

ICH : The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

## REFERENCES:

✓ 21 CFR Part 211.

✓ Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. ICH Q7 Good Manufacturing Practices Guide for API's