

Standard Operating Procedure

Title: Management and Control of Contract Work

Table of Contents

1.	Control of Contract Manufacture and Packaging for finished Products.....	2
2.	Flow Chart – Process of Contract Work	4
3.	Contract Manufacture by Site on behalf of Other Companies	5
4.	Summery of Changes	5

General

cGMP and all aspects of this procedure must be adhered to ensure production of a quality product.

Separate documentation is to be prepared for each presentation of each type of product, but repeat operations are referenced to the original documentation as long as there has been no change in items listed. However any changes to established contract work are to be handled in a similar manner to new contract work.

Contractors must be advised of any planned significant changes, which can affect the quality of the products subject to the Agreement, e.g. changes in site of manufacture, formulation, processing equipment.

Technical Service Department will liaise with Regulatory Department to determine if Regulatory approval is required for manufacturing or packaging at an external site.

1. Control of Contract Manufacture and Packaging for finished Products

1.1. Scope

Documentation

Several forms of documentation are associated with contract manufacture:

1.1.1 **Master File.** This file may contain the following documents: Specifications, Formulation, Manufacturing Instruction, Control Methods, Raw Material/Packaging specifications.

1.1.2 Quality Assurance Agreement

A written and binding agreement between Contract Giver and the Contract Acceptor that clearly defines the roles and responsibilities of both parties for a service, product, project or study and covers the following areas:

- Definition
- Introduction and Scope
- Processing, Analysis, Packing and Release
- Quality Assurance and Quality Control
- Release Procedure and Transportation
- Product Recall
- Product Quality Complaints
- Post Marketing Stability Studies
- Annual Product Review
- Quality Management

A Quality Assurance agreement is to be drafted by Quality assurance Department, using **TEM-100** and checked by the Technical Service Department.

The Quality Assurance Manager will sign the QA Agreement.

The signed QA Agreement is forwarded by the Quality assurance Manager to the Contractor and confirmation of the requirements of the Agreement obtained from the Contractor, (usually by signing and returning an extra copy of the Agreement).

The signed Quality Assurance Agreement is to be logged into the Register of Contracts and stored in the Manufacturing safe.

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2. Flow Chart – Process of Contract Work

