

Standard Operating Procedure

Title: Management and Control of Contract Work

Department	Quality Management	Document no	QMS-110	
Prepared by:		Date:	Supersedes:	
Checked by:		Date:	Date Issued:	
Approved by:		Date:	Review Date:	

Document Owner

Quality Assurance /Supply Chain Manager

Affected Parties

All Sydco colleagues in QA/Procurement/Operation/Technical service teams.

Purpose

This SOP describes the different aspects of Contract Work with reference to Sydco:

1. Control of contract manufacture and packaging for Sydco's products.
2. Contract manufacture and packing by Sydco on the behalf of other Companies
3. Contract Supply Procedure.

Scope

Responsibility for the procedures set out in this SOP is as follows:

- Quality Assurance Manager
- Technical Service Manager
- Operations Manager
- Procurement Manager

Definition

TPM	Third Party Manufacture Dispatch Report
cGMP	Current Good Manufacturing Practice

Related Documents

TEM-105	Third Party Manufacture Dispatch Report Template
TEM-100	Quality Assurance Agreement Template
WAR-020	Dispatch of Goods From Warehouse
QMS-080	Audits

EHS Statement

There is no EHS impact by this documented procedure, however EHS issues need to be reviewed in the selection of new contractors.

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- 1.1.3 **Toll Agreement**, which will outline the cost associated through Supply Chain and a Service Level Agreement, which is raised at the discretion of the Supply Chain area.
- 1.1.4 **Third Party Manufacture Dispatch Report (TEM-105)**, is to be raised by the Supply Chain area.
- 1.1.5 **Purchase Order**
A Purchase Order must cover all contract work.
The Procurement staff will ensure that:
- (a) Every Purchase order for the work described contains the appropriate information.
 - (b) Every purchase order for the work described in the agreement makes reference to the appropriate Material Code number.
 - (c) Any alteration in the process becomes the subject of an amendment of the agreement.
 - (d) No external work on products is carried out without the requirements of this SOP being met.
 - (e) The work order specifies guidelines to yield required, efficiency of the work, overall cost/unit, delivery details and time.
- 1.1.6 **Material Code number**
The Technical Service Department will allocate a Material Code number for the goods or service being ordered. This Material Code number is to be featured on the order.
- 1.1.7 **Production Documents**
The contractor is responsible for devising suitable Production Documents on which the operations of packing for shipping to the contractor, counts, bulk batch numbers, shipping details, etc., together with received details of the completed work, together with a reconciliation can be recorded. The originals of these documents are to be approved by the contract giver.
- 1.1.8 **Warehouse**
On receipt of the finished goods from the Contractor, the Receiving Warehouse books in the material.

The documentation must be tallied and include reconciliation of reject materials. This reject material is not returned (unless requested), however should unusual quantities of rejects be associated with the batch, Contract giver should be advised and may examine these rejects before their destruction by the Contractor.
It is critical that care be taken to maintain the segregation of any separately packed material or batches.
- 1.1.9 Quality Assurance examines, passes and/or rejects material on the basis of approved specifications.

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3. Contract Manufacture by Sydco on behalf of Other Companies

- 3.1. Sydco may accept contract work in its field of competence, providing the product presentations are compatible with existing equipment, not in direct competition with Sydco products and capacity exists.
- 3.2. Should Bulk unlabelled or Sydco-labelled product be required, this is ordered on a Purchase Order, and does fall under this SOP.
- 3.3. If the product is to have the Contract Givers' name on the label, a written GMP/Toll Agreement is required. This is to be signed by responsible personnel at the Contract Giver site and by Sydco.
- 3.4. The Company Secretary will hold a copy of this Contract.
- 3.5. Sydco will supply tested, passed product as per the Agreement together with a Certificate of Analysis. (Production documents will only be supplied where requested.)

4. Summery of Changes

Version #	Revision History
QMS-110	New