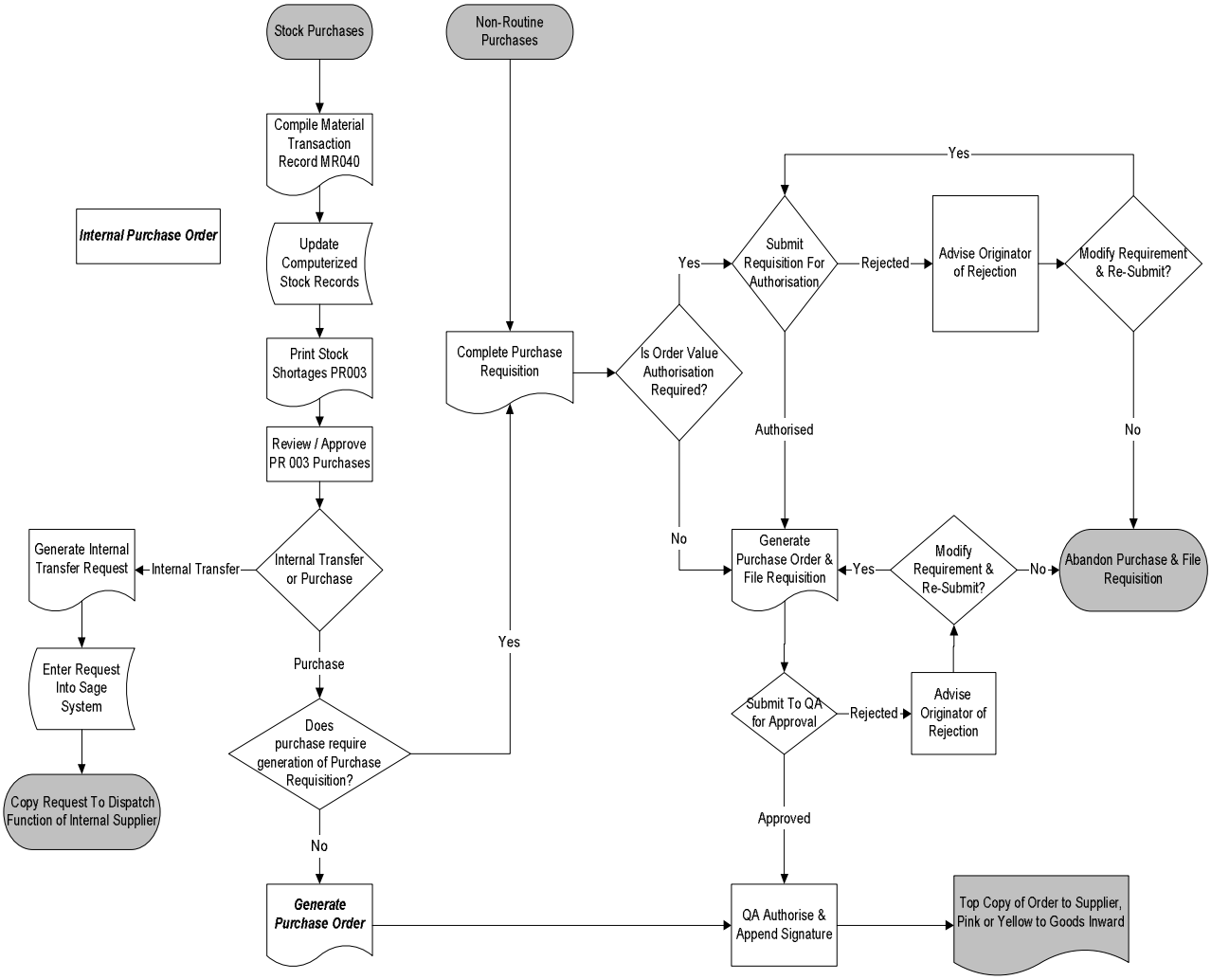
PURCHASING AND ORDER PROCESSING



1.0 SCOPE

To establish and maintain a documented system within which all goods and services which affect product quality are purchased and conform to Biosil specifications in accordance with the requirements ISO 13485, 21 CFR Part 820 – Quality System Regulation and Council Directive 93/42/EEC Annex II Sect 3.2d.

2.0 DOCUMENTS RELATING

QP 003 Contract Review
QP 007 Supplier Approval
QP 008 Preparation of Purchased Material and Service Specifications
QP 017 Control of Incoming Goods
QP 026 Handling, Storage and Preservation

3.0 RECORDS UTILISED

The table below indicates each record sheet associated with this procedure and responsibility for storage.

Ref	Title	Custodian
MR 040	Materials Issue/Return Record	Quality Dept
MR 055	Materials Transfer Record	Quality Dept
QR 132	Certificate of Conformity	Quality Dept
PR 001	Purchase Requisition	Administration
PR 002	Purchase Order form	Administration
PR 003	Stock Code Shortages Report (routine purchases)	Administration
SR 007	Shipping Note	Shipping / Despatch Dept
N/A	System Audit Report	Administration

4.0 RESPONSIBILITY

4.1 **Heads of Departments** shall be responsible for:
a) The authorization of their Departmental Purchase Requisitions subject to the financial limits as stated on the PR 001.
b) Requesting Internal Transfers between Biosil sites.

4.2 The General Manager[1] and Finance Manager shall be responsible for the approval of all purchase requisitions, above the financial limits as stated on PR001.

4.3 The Operations Manager or Nominated Deputy shall be responsible for:

a) The approval of Stock Code Shortages Reports (subject to a financial limit authorised by the General Manager).
b) The setting of maximum and minimum stock levels for routinely used materials.

4.4 The *Quality Department* shall be responsible for:

[1] In the event of the unavailability, a member of Management with executive responsibility can sign on behalf of the General Manager

a) The verification of purchasing data on all purchase orders and specifications.
b) Ensuring that all controlled items and critical services are purchased only from approved suppliers and subcontractors.
c) Generation of a Certificate of Conformity and/or Certificate of Compliance as appropriate for internal transfers and sales when required within purchase specifications or sales orders.

4.5 The Quality Control Inspector shall be responsible for the expedition of overdue orders.

4.6 Administration shall be responsible for

a) Contacting suppliers to confirm both the receipt of purchase orders and expected delivery date
b) Notifying QA ***Dept*** of internal transfers or sales orders of goods to enable generation of Certificate of Conformity / Certificate of Compliance as appropriate.

Note: In the event of unavailability of the personnel stated above a member of management shall either act as deputy or appoint a suitable trained member of staff.

5.0 STOCK CONTROL SYSTEM

5.1 Each routinely purchased item has a unique stock code prefixed with the letter A. Non stock items such as stationery, maintenance consumables, etc. shall be purchased against service codes as determined by the Finance Manager.

5.2 Routinely purchased items shall be subject to a system of computerised stock control. The minimum information held on the computer system for each item shall be :

a) Supplier Name and Address (Preferred Supplier)
b) Stock Code
c) Description
d) Product Group
e) Storage location
f) Unit of Measure
g) Max & Min Stock
h) Re- Order qty
i) Stock balance (free and allocated)
j) Cost Price

5.3 Receipt of purchased materials shall be recorded on the "For office use only" section of the PR 002 Attachment from which the computer system shall be subsequently updated.

5.4 Other internal stock movements shall be recorded on MR 040 - Materials Issue/Return Record and MR 055 Materials Transfer Record which shall be held at appropriate locations.

5.5 Materials Issue/Return and Transfer Records shall be entered onto the computerised accounts system and transferred to the QA department when fully complete.

5.6 On a minimum twice weekly basis a PR 003 - Stock Code Shortages Report (routine purchases) shall be generated indicating purchased items whose stock levels have fallen below the stated minimum level.

5.7 If amendment to the maximum / minimum stock levels or re-order quantities is required then these shall be recorded and initialled on the PR 003 Stock Code Shortages Report. The Operations Manager (or nominated deputy) shall then identify and approve the required

purchases and a PR001 shall be raised if value of the item on PR003 requires financial authorisation.

5.8 The report shall be returned to the Administration Department to enable amendment of the maximum / minimum stock levels or re-order quantities and generation of Purchase Orders.

6.0 REQUISITIONS FOR NON-ROUTINE PURCHASES

6.1 Where non-routine purchases are identified, e.g. for replacement equipment, a PR 001 – Purchase Requisition shall be authorised to the financial limit as stated on the PR001 by the relevant Head of the Department wishing to make the purchase.

6.2 The requisition shall include the following information (where known):

a) The name of the supplier, supplier reference and the quantity required.
b) The suppliers part number
c) A clear and unambiguous description of the item required.
d) The current price for the purchase.
e) Any additional instructions e.g. certificate of conformity required etc.;
f) The name of the originator and date.

7.0 GENERATION OF PURCHASE ORDERS

7.1 Sequentially numbered purchase orders shall be generated by the Administration Department upon receipt of suitably approved Purchase Requisitions or Stock Code Shortages Reports. These documents should be cross-referenced for traceability purposes.

8.0 APPROVAL OF PURCHASE ORDERS

8.1 The Q.A. Deputy (Or other suitably trained QA Personnel) shall approve all purchase orders to verify that all data affecting quality is adequate. The applicable purchase requisition shall be attached to the purchase order when passed to QA. Data shall include the following checks, where applicable:

ROUTINE PURCHASES	
Check:	Referenced in:
Precise identification of the product (type, class grade, etc.)	applicable Biosil part number
Suppliers reference number(s)	Purchase Specifications.
Purchase specification requirements	Purchase Specifications
Reference to national or international standards	Purchase Specifications
That the correct Biosil delivery address is stated	n/a
NON-ROUTINE PURCHASES	
Is the supplier approved?	Purchase Requisition
Is the level of specification adequate	Purchase Requisition
For the purchase of new equipment, is the qualification status known	Purchase Requisition
Is calibration or validation required	Purchase Requisition
Where subsequent calibration and maintenance is required, this shall be annotated on the pink/yellow copy of the Purchase Order	Purchase Requisition

8.2 For purchases which are specifically to Biosil's design, a 'SPECIMEN' copy of the purchase specification together with any associated drawings shall be provided to the supplier.

9.0 DISTRIBUTION OF PURCHASE ORDERS

9.1 Distribution for approved Purchase Orders shall be:

Top Copy (White)	- Supplier
2ND Copy (Pink-Ashby, Yellow-Cumbernauld)	- Quality Control Inspector at relevant site for verification purposes upon receipt of goods following completion of 9.2.

9.2 Following QA Approval the second copy of the purchase order will remain with Administration until they have contacted the supplier to confirm both the receipt of that purchase order and expected delivery date. Confirmation of these requirements is to be documented onto the second copy of the purchase order which will then be passed to the QC Inspector.

9.3 The Quality Control Inspector shall file the pink/yellow copy pending delivery of the item(s).

10.0 ACTIONS UPON RECEIPT OF GOODS

10.1 Upon receipt of the goods, and subject to inspection procedures, the Quality Control Inspector, or nominated deputy, shall attach the supplier's delivery note to the purchase order and forward to Administration.

10.2 The receipt details shall be entered onto the accounts system and the Purchase Order and Delivery Note shall then be filed.

11.0 PART DELIVERIES

11.1 The Quality Control Inspector shall enter the following details in the appropriate section of the purchase order (PR002 attachment):

a) Date of receipt
b) Item No (if applicable)
c) Quantity received
d) Expiry date
e) Balance outstanding
f) Accept or reject
g) Signature

12.0 INTERNAL TRANSFERS (Non US components only)

12.1 The Internal transfer process is only applicable to components which are not incorporated into US product. The purchase specifications define which components are subject to internal transfer process.

12.1 Internal Transfer Requests between Biosil sites shall be made via ***written or electronic communication.***

12.2 Administration will enter the details from the communication into the computerised accounts system, noting the system order number upon the ***internal transfer request*** for reference.

12.3 When the items are ready to be despatched a SR 007 – Shipping Note – is raised with all relevant details entered. The shipping note shall be passed to QA to review and generate a Certificate of Conformity / Certificate of Compliance as required. Where it is necessary to initiate internal transfer of items between sites which are not documented on purchase specifications, each transfer requirement will be assessed on an individual basis.

12.4 On transfer of goods to courier the pink/yellow copy of the SR 007 and the original QR 132 is retained at the despatch site whilst the white copy of the SR007 is sent with the goods together with the specimen copy of the certificate of conformity where applicable.

12.5 On a daily basis the site Goods In departments must routinely run An Inter Warehouse Transfer Report within SAGE. WI 010-09. This will highlight to the receiving sites goods in department any products arranged for transfer between the sites that day.

12.6 On receipt the Quality Control Inspector ***or despatch operator,*** shall confirm acceptance of the goods on the PR 002 attachment and then pass to Administration who will make the transfer from the 'In Transit' Warehouse to the 'Active' Warehouse and amend the 'on-order' quantities on the computerised accounts system.

12.7 For any goods highlighted as remaining on the transit warehouse report for more than one consecutive day without physical receipt or instruction of a delay, a query should be raised with the alternative sites shipping department.

13.0 ORDER PROGRESSING

Reports can be printed from the computerised accounts system giving the status of outstanding orders. These may be used to expedite orders that are shown as overdue.