INTERNAL AUDITS

This procedure defines the system in operation at the company for carrying out planned internal audits, and / or reviews, necessary to verify compliance with all aspects of the defined quality program. It is the responsibility of the Quality Engineer to oversee all requirements of this procedure, with delegated nominees adding to the audit team if and where necessary.

Descriptions

Overview audit - carried out when triggered by the system an overview audit is due. The audit calendar can be view in Intrastats ISO → Audit schedule QC 17.

Each section of the company's system, as described in the manual, is audited at least once per annum. Further audits are dependant upon previous results. Product audits will also be performed as dictated by company and regulatory needs. The auditor will diligently check that the procedures in operation are being complied with, and are suitable and effective. Checklists may be generated for use in the audit, and would therefore form the basis of the audit records; cognisance of previous audit results is taken when generating any checklists.

Where corrective actions are needed as a result of the audit, they will be detailed, in a follow-up Issue linked to the primary audit,and the corrective action / completion date agreed.

Subsequent follow-up audits will take place within one week of these effective dates, to assess compliance. The auditor will formally close out the audit after having been assured that follow-up actions have been satisfactorily completed. All results will are recorded in the issue's and linked issues.

Overview Mini-audit Intrastats Generates Issues when an audit is due, it will be carried out within 2 months of being generated, completed checklist will be uploaded to the issue by the person responsible for carrying out the audit. Any non conformance's / corrective actions shall be tracked by related Issues to the original Issue.

Overview audits issues shall be reviewed by management before being filed to history.

History of audits can be retrieved by pulling up the history of the Rolling Issue, or the appropriate header in intrastats

Each Overview Audit document is tagged in the Admin panel as to which sections of the QMS system the audit relates to.

Mini audit – Each Underlying process depending on the risk and type of process can be allocated a Rolling Audit Issue. As each process has an allocated Employee, any other employee can perform a mini audit. Most Mini audits contain instructions on carrying out the auto within the issue generated

Weekly Management review of rolling Tasks and Audits will either close the Mini Audit, or generate further actions if required, Further action Issues are linked to the original audit issue. And tracked until completion.

History of a Mini Audit / associated tasks are linked to every mini audit, and available from the related Issues.

On completion of the weekly management review, the Task / Audit completion history screen is displayed, where any outstanding Issues from previous tasks / audits are highlighted for re-review.

Procedures will be periodically assessed for possible changes needed
NB may need approval of Assessment body

BOARD MEETING MANAGEMENT REVIEW
Process 7846 Rolling Task 746
Senior Management at the Official Board Meetings, together with other management staff as deemed appropriate, will review the System and its processes at least once every year +/- 2 Months. The review agenda will constitute, as a minimum, the following points:

a. Follow-up actions from previous reviews.
b. Customer feedback.
c. Results of internal audits.
d. Process and product performance.
e. Preventive and corrective actions.
f. Possible system changes.
g. Recommendations or improvement.
h. Any other business

In addition, each of the following points, as a minimum, will be addressed:

1. Contract review / Picking, Packing & Despatch
2. Purchasing controls
3. Supplier / subcontractor performance
4. Storage & Stock control
5. Customer complaints
6. Calibration
7. Documentation & records
8. Training
9. Int. audits & corrective actions
10. Review of responsibilities
11. Resources required
12. New products etc.
13. Quality planning
14. Achievement of Quality Policy
15. Advisory notices & recalls
16. Vigilance system (Complaints, Repair levels, Surveillance reply cards)
17. Changes to the Management system
18. Changes to CE marked products

The review will be minuted and a plan of action will be generated from it. Activities undertaken in the plan of action will be timely, and subsequently verified by the Managing Director.

Weekly Management Reviews

Where possible a weekly review of **ALL** tasks and audits across all departments and areas is undertaken, but never more than 3 weeks apart in special circumstances.

As per Mini Audits above.

Weekly Management review of rolling Tasks and Audits will either close the Mini Audit, or generate further actions if required, Further action Issues are linked to the original audit issue. And tracked until completion.

History of a Mini Audit / associated tasks are linked to every mini audit, and available from the related Issues.

On completion of the weekly management review, the Task / Audit completion history screen is displayed, where any outstanding Issues from previous tasks / audits are highlighted for re-review.

Product Reviews post market surveillance

Manufactured products: Each range shall be reviewed once per year + 2 Months – depending on the timing of the triggering Issue to perform the Product review (Task ID 50)

Each Product Type will have a post market surveillance report created, as PER :VM3COP27.11

Stock References will be confirmed as included in the review:

All Related Suppliers will be confirmed, and checked the supplier review is upto date

Sales Information will reviewed

Country Sales will be reviewed

Returns and QA Failures will be reviewed. (Note due to the size and quantity of information within the Returns and QA reviews a summary is listed in the Final Post Market surveillance report).

Any Design changes will be reviewed

Instruction Manual changes will be reviewed

Labels will be reviewed

Other Documentation changes will be reviewed

All internal Issues relating to the Product range will be reviewed: (again due to the quantity of information contained within the Issue review, only the ID and subject will be listed in the Final Post Market surveillance – however during the review and afterwards the entire issue history is available)

a Web serach for Clinical / FDA reports will be performed to see if there are any unknown risks (maybe with competitors products) or if the technology is outdated.

Issues created during the review will be eveluated to see if the Risk file requires updating.

Management Product Reviews General

Rolling Issues to review the ‘New Repair Code’ information across all products supplied. Both In house produced Items or those supplied by other manufacturers will appear on this list.

The report screen displays any new type of fault as discovered by QA/Returns engineers.

During the review the repair code is either linked to a clean code, or a new clean code is produced.

If its a In house product and there is a new clean code, an entry into the Risk file is made (now automatically) for further investigation to evaluate the potential new risk presented.

Rolling Task ID 750 Rolling Audit 751

QA Reviews (rolling task 727 Rolling Audit 729)

All the previous months QA is reviewed – any high % of failures a non conformance issue is raised to examine further the potential problem.