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Hi-Tech Lab
Quality Review
Monthly | Volume 1, Number 4 | August 2008

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Hi-Tech Lab Quality Review provides a forum for open and responsible discussions relating to quality of pharmaceuticals. Its mission is to promote "Quality Culture".

Editor:
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ISO 9000

20 Elements of ISO 9000

1. Management responsibility
2. Quality system
3. Contract review
4. Design control
5. Document and data control
6. Purchasing
7. Control of customer-supplied product
8. Product identification and traceability
9. Process control
10. Inspection and testing
11. Control of inspection, measuring and test equipment
12. Inspection and test status
13. Control of non-conforming product
14. Corrective and preventive action
15. Handling, storage, packaging, preservation and delivery
16. Control of quality records
17. Internal quality audits
18. Training
19. Servicing
20. Statistical techniques

1. Management responsibility

1.1 Quality Policy

Prepare a policy document showing company's commitment to quality. It should be understood and implemented at all levels.

1.2 Organization

1.2.1 *Responsibility and authority*

Identify people whose work affects quality stating their responsibilities and relationships.

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Monthly | Volume 1, Number 4 | August 2008

1.2.2 *Resources*

Assess and provide the resources needed to maintain quality.

1.2.3 *Management representative*

Appoint a manager responsible to coordinate and report the quality system.

1.3 Management review

Meet regularly to review the system. Keep record of each meeting.

2. Quality system

2.1 General

Establish a system that ensures production in accordance with the company's plan. A system manual and procedures should explain how each activity is to be carried out.

2.2 Quality system procedures

a) Prepare documents and procedures consistent with the requirements of ISO 9001, 9002 or 9003 and the company's stated quality policy stating how work is to be carried out.

b) Effectively implement the quality system and the procedures (which should refer to the Quality Manual, Procedures, and Work Instructions, defining how an activity is to be performed).

2.3 Quality planning

Prepare a documented plan of each work area and activity.

3. Contract review

3.1 General

Maintain, document, and coordinate procedures to review contracts and orders before they are finalized.

3.2 Review

a) Clarify customer's requirements
b) Resolve discrepancies before finalizing
c) Confirm the company's capability to execute the order/contract

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Monthly | Volume 1, Number 4 | August 2008

3.3 Amendment to a contract

Establish procedure for amendments and their communication to and coordination with concerned persons.

3.4 Records

Maintain the records of the reviews and checks made to the order/contract.

4. Design control

4.1 General

Establish procedures to control the quality of each design.

4.2 Design planning

Plan details of activities for each design.

4.3 Organizational and technical interface

Establish in writing how people in different departments will review the plans and effectiveness of each design.

4.4 Design input

Establish applicable requirements in writing.

4.5 Design output

Documented evidence in written briefs.

4.6 Design review

Hold design review at appropriate stages.

4.7 Design verification

Take measures to verify correctness in reviews.

4.8 Design validation

Authorize the conformation to customer's requirements.

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4.9 Design changes

Must be authorized before implementation.

5. Document and data control

5.1 General

Establish, maintain and control quality related documents and data pertaining to ISO 9000.

5.2 Document and data approval and issue

a) To be reviewed and approved for adequacy by the authorized personnel prior to issue.
b) Keep a master list of current documents.
c) Ensure availability at concerned places.
d) Language should be understandable by the user.
e) Ensure the retrieval of out-of-date documents are removed promptly from all places of use.

5.3 Document and data changes

a) Review documents on routine intervals.
b) Review and approval by the same function who authorized the original documents.
c) Written amendments in documents.

6. Purchasing

6.1 General

Establish and maintain procedures to ensure that purchased product conform to specified requirements.

6.2 Evaluation of sub-contractors

a) Evaluate and select subcontractors on the basis of their ability.
b) Define the controls (performance reports, audits, etc.) of sub-contracted parts.
c) Maintain quality records of qualified/acceptable sub-contractors.

6.3 Purchasing data

The Purchase Orders should clearly describe what is being ordered. The data include: type, class, grade, specifications, drawings, inspection instructions, etc. of parts.

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6.4 Verification of purchased product

a) Supplier verification at sub-contractor's premises (if required then it should be mentioned on the Purchase Order).
b) Customer verification of sub-contracted product (if required by the contract).

7. Control of customer-supplied product

Ensure safety and integrity of customer's product, while it is in the company's possession. For this:

a) Establish and maintain procedures for the control of verification, storage and maintenance of customer-supplied product.
b) Product which has been lost, damaged or is unsuitable for use shall be recorded and reported to the customer.

8. Product identification and traceability

Establish and maintain procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation. This identification shall be recorded by labelling (e.g. stamps, stickers, travel cards, etc).

9. Process control

Production, installation and servicing processes should be carried out under controlled conditions, i.e.:

a) Prepare work procedures/plans.
b) Use suitable equipment and working environment.
c) Compliance with reference standards/codes, quality plans and documented procedures.
d) Monitoring and control of suitable process parameters and product characteristics.
e) Approval of processes and equipment, as appropriate.
f) Establish workmanship. Take samples, if needed.
g) Suitable maintenance of equipment to ensure consistent process capability.

Special processes (those which can not be checked) will require continuous monitoring, qualification of associated operators, equipment and material. Records shall also be maintained.

10. Inspection and testing

10.1 General

Establish and maintain procedures for inspection and testing activities at receiving, in-process, and final inspection.

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10.2 Receiving inspection and testing

a) Carry out inspection in accordance with the quality plan and the procedures.
b) The controls depend on the sub-contractor's quality and recorded evidence of conformance.
c) In case of urgent production release, it should be properly identified and recorded.

10.3 In-process inspection

a) Inspect as per written procedure.
b) Hold product until inspection is completed or verified.

10.4 Final inspection

In accordance with the quality plan and written procedures the product should be released after proper verification.

10.5 Records

Proper records of inspections should be maintained.

11. Control of inspection, measuring and test equipment

11.1 General

Establish and document procedures to control, calibrate and maintain the measuring and test equipment (including software) to demonstrate their correctness.

11.2 Control procedure

a) Evidence of accuracy and precision of the measuring equipment to the required quality standard.
b) Calibration activity traceable to national/international standards.
c) Define calibration process.
d) Show calibration indicator on equipment.
e) Maintain calibration records.
f) Define validity of calibration.
g) Ensure environmental conditions of calibration.
h) Detail out the procedures for safe handling, preservation and storage of equipment
i) Safeguard test equipment.

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12. Inspection and test status

The identification of inspection and test status should be shown, as defined in the company's quality plan or procedures, through all stages of production, installation and servicing in order to ensure that only product of passed quality is dispatched, used or installed.

13. Control of non-conforming product

13.1 General

Establish and document a procedure to control the non-conforming products. The control should provide for identification, documentation, evaluation, segregation, disposition of the non-conforming product, and for notification to the functions concerned. Prevent faulty products getting to the customer.

13.2 Review and disposition of non-conforming product

a) Define responsibilities at all levels in case a non-conforming product has been identified.
b) It should be reviewed in accordance with the documented procedures. Rework, repairs, and rejections should be clearly done and identified according to the standard procedures.
c) Repaired product should be re-inspected.

14. Corrective and preventive action

14.1 General

a) Establish and document procedures to take corrective actions to prevent defects occurring in the product, process, and system.
b) Incorporate and implement the changes in the procedure which become necessary to prevent the recurrence of the defects.

14.2 Corrective action

a) Investigate the customer complaints and in-house non-conformities.
b) Investigate the causes of non-conformities.
c) Identify the actions to be taken.
d) Apply the controls for effectiveness.

14.3 Preventive action

a) Use appropriate sources of information (such as quality audit reports) to detect, analyze and eliminate potential causes of non-conformities.
b) Take steps needed to deal with any problem.
c) Control to ensure effectiveness.
d) Actions taken should be reported to the management.

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15. Handling, storage, packaging, preservation, and delivery

15.1 General

Establish procedures to prevent deterioration of products.

15.2 Handling

Established procedures to prevent damage or deterioration during handling.

15.3 Storage

a) Safe storage before they are delivered.
b) Authorized receipts and dispatch.
c) Stock levels should be assessed.

15.4 Packaging

Packing and its material and marking should be carried out according to specifications.

15.5 Preservation

Appropriate methods for preservation and segregation of product and its material while it is in company's custody should be followed.

15.6 Delivery

Establish procedures for safe delivery of products.

16. Control of quality control records

Establish and document procedures for identification, collection, indexing, access, filling, storage, maintenance and disposition of quality related records.

Pertinent records of the sub-contractors should also be controlled. Records should be legible, retrievable, and safe. Retention time should be clearly specified and complied with.

17. Internal quality audits

Establish and document procedures for planning and implementing internal quality audits (by the company's management) to verify whether quality activities and related results comply with the quality policies, and determine its effectiveness.

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The audits should be scheduled. They should be carried out by persons independent of those having direct responsibility for the facility being audited. Audit report should be published. Corrective actions should be taken as suggested.

Follow-up audit should be carried out to verify and record implementation and effectiveness of the corrective action.

18. Training

Establish and document procedures for identifying training needs for all those whose job affect quality of product and provide for the training of all personnel performing activities affecting quality.

A job should be assigned to the personnel according to their education, training and experience. Records must be maintained.

19. Servicing

Establish and document procedures for performing, verifying and reporting after-sales-services.

20. Statistical techniques

20.1 Identification of need

Identify the need for the use of statistical techniques for establishing, controlling, verifying and improving process capability and product characteristics.

20.2 Procedures

Implement and control the application of the statistical techniques.