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Quality Records

Purpose

This procedure establishes a system of record retention that meets legal and contractual requirements and maintains accurate records of production and the conditions under which each product was produced.

Scope

This procedure applies to all records referenced in quality system procedures.

Definitions

Quality Records Documents that demonstrate that quality measures have been achieved and that the quality system is operating effectively.

Retention Period A specific timetable for storage of specified records.

Responsibilities

DOC ORIG Document Originator

QUAL MGR Quality Manager

DEPT SUP All Department Supervisors

Procedures

1 - DOC ORIG Capture and Identify the Moment

With the appropriate data container available, the document originator captures the data or information to enter into the record to be created. The data is legible (4.2.4[2]), clearly identified (4.2.4[2], 4.2.4[3]) as to what it pertains to, when it was collected, the method of collection, by whom the collection was made and other data as required. **2 - DOC ORIG**

2 - QUAL MGR Specify Retention Requirements

Reviews and approves quality procedures for records to be retained, the person or department responsible, and the minimum retention time required for quality assurance purposes.

3 - DEPT SUP Ensure Proper Document Storage

Ensures that records are stored (4.2.4[3]) in a way that minimizes deterioration or damage and prevents loss (4.2.4[3]). Whenever possible, the records are stored in our EDMS to facilitate easy retrieval (4.2.4[2], 4.2.4[3]) for those who need access to the data.

4 - DEPT SUP Provide for Easy Retrieval

Identifies, indexes, and files records for easy retrieval.
"Superseded", "Expired", or "Rescinded" (4.2.3[3]g[1])

5 - DEPT SUP Retain Records as Specified

Retains record for the time period (4.2.4[3]) specified for each procedure.

6 - QUAL MGR Allow for Customer Review

Upon request, makes quality records available to customers for review.

7 - DEPT SUP Purge Outdated Records

Records that are no longer needed and have passed the time period specified for each record are disposed of by deletion or purging from our system by the end of the next quarter from their retention period (4.2.4[3])

References

Configuration Management QSP-4.3.101

Document Control - External Documents QSP-4.2.102

QUALITY RECORDS QSP-4.2.103

Policy References

QPM-301 Rev. C

Revision Notes:

- Rev. C Changed Policy Reference from QPM-301 Rev A5 to QPM-301 Rev C
- Changed errant reference from QSP-4.2.104 to QSP-4.2.103
- Changed from PowerWay to .PDF format.
- Updated changes made to numbering on reference documents.