

Do the CGMP regulations permit the destruction of an internal quality assurance audit report once the corrective action has been completed?

The CGMP regulations (21 CFR 210 and 211) for finished pharmaceutical manufacturing do not specifically address the requirement to conduct, or to keep records of, internal quality assurance audits. If the report in question were from a routine audit to verify that the firm's quality system is operating as intended, then it would be acceptable if the firm elected to discard the report once all corrections have been verified.

However, any documentation of corrective action as a result of such an audit would have to be retained (see 211.180 and 211.188). For example, if a routine internal audit finds a problem with a mixing step and the outcome is a change in mixing time, all affected procedures, including the master production record, are to reflect the necessary changes, and such records are subject to FDA inspection as usual. Any investigation into the impact this problem had on related batches is to be retained and also made available for inspection by FDA (see 211.192).

In addition, any reports of investigations or evaluations prepared in response to, for example, a product complaint (211.198), vendor qualification (211.84), periodic review of records and data (211.180(e)), and a failure investigation (211.192) are not internal audits as discussed above. Such records are subject to FDA inspection and must be retained for at least the time specified in the CGMP regulations (see 211.180).

References:

- Preamble to the *Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding* regulations; Federal Register, September 29, 1978 (vol. 43, no. 190), page 45015, paragraph 4 <http://www.fda.gov/cder/dmpg>
- 21 CFR 211.84: Testing and approval/rejection of components, drug product containers, and closures
- 21 CFR 211.180: General requirements
- 21 CFR 211.192: Production record review
- 21 CFR 211.198: Complaint files
- Compliance Policy Guide Sec. 130-300, (7151.02) http://www.fda.gov/ora/compliance_ref/cpg/cpggenl/cpg130-300.html

Find more Questions and Answers from FDA at:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124780.htm>