



Post inspection continuation of Compliance Management action

In situations where prior inspection of a manufacturer / distributor has identified critical and/or major deficiencies resulting in escalation to the compliance management process, a re-inspection may be performed to ensure completion of actions in accordance with the agreed remediation program.

Further deficiencies identified during the re-inspection will be independently review by a senior or expert inspector, and the final classification confirmed in writing within 14 days. The timescale for responding to the deficiencies will be confirmed in the post inspection letter (typically 21 days).

Where the company's remediation plan remains in progress, the original deficiencies resulting in compliance management escalation continue to be valid for consideration of action until it is confirmed that effective remedial actions have been implemented (usually upon re-inspection). The company will have been previously notified of compliance management objectives; these can be clarified by the inspector on request.

The re-inspection findings will be provided to the Compliance Management Team (CMT) for review. Further correspondence on the outcome of the inspection in terms of continuing compliance action will be communicated to the company separately by the CMT. This may take place following receipt and assessment of the company's post inspection responses.

The on-going compliance management review will continue to determine whether there are grounds for the Licensing Authority to consider formal regulatory action. This may be based upon the current inspection findings, inadequacy of proposals to correct the inspection findings, or failure to implement commitments in an effective or timely manner.

It is very important for the company to maintain open communication channels with the site inspector and CMT throughout the process, and notify any significant changes in GMP compliance (positive or negative), including delays in implementing corrective action commitments, in a timely manner.