Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Post inspection consideration of Compliance Management action – Active Substance manufacturer

Inspections where major and/or potentially critical GMP / GDP deficiencies are identified may be escalated to senior Inspectorate staff for consideration under the Compliance Management process. The objective of this non-statutory process is to escalate the inspection case management and direct companies towards a state of compliance, thus protecting public health and avoiding the need for regulatory action.

The inspection case management actions required may include meetings and correspondence with company senior management to alert them to the compliance concerns, clearly outlining the consequences of continued non-compliance, and close monitoring of compliance improvement work through inspections and written updates from the company.

The initial and on-going Compliance Management review will also determine the need for referral to the Licensing Authority to consider the issuance of an EU Statement of Serious Non-Compliance with GMP / GDP. 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.

The issuance of a Statement of Serious Non-compliance with GMP will prevent batch certification and release to market of medicinal products in the EU containing the active substance from the date of publication, unless otherwise indicated. Any previous GMP certificates will be withdrawn.

Following independent review by a senior or expert inspector, the final classification of deficiencies will be confirmed in writing within 14 days. The company will have 21 days from the date of receipt to respond with their proposals for corrective action. Any further compliance monitoring actions will be communicated as separate correspondence.

It is very important for the company to maintain open communication channels with the site inspector and Compliance Management Team (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. Contact details will be provided in the initial correspondence from CMT to the company.

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