Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Site name

Site address

Dates of inspection

Post inspection consideration of Compliance Management action – UK MIA, MIA(IMP) and overseas manufacturers

The inspection conducted at the above named facility has identified major and/or potentially critical GMP / GDP deficiencies which will 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 consider whether there are grounds to require the issuance of a Statement of Serious Non-Compliance with GMP or, **for sites in the UK,** grounds under regulation 26 of the Human Medicines Regulations 2012 (as amended) for the Licensing Authority to take formal regulatory action against your licence. 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 implications of formal regulatory actions are as follows:

- **The issuance of a Statement of Serious Non-compliance with GMP** will prevent batch certification and release to market of medicinal products from the date of publication, unless otherwise indicated. Any previous GMP certificates will be withdrawn.
- **For sites located in the UK: Action against your manufacturing licence or authorisation** (either suspension in full or variation to remove specified activities, facilities or sites), which in most cases is preceded by a notice period of at least 28 days. It is a criminal offence under regulation 34(1) of the Human Medicines Regulations to manufacture or distribute medicinal products without the required licence.
- **For sites located in the UK: Action to remove named persons from a manufacturing authorisation** (e.g. Qualified Persons). A Qualified Person removed from a manufacturing authorisation would not be permitted to certify medicinal products manufactured under that authorisation. Furthermore, unless there are other persons already named on the manufacturing authorisation as responsible for the relevant role, the licence holder will also have to submit a variation to propose a replacement in order to maintain a valid authorisation.

Following independent review by a senior or expert inspector, the final classification of the deficiencies will be confirmed in writing within 14 days. You will have a further 21 days from the date of receipt to respond with your 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.