Medicines & Healthcare products Regulatory Agency

Compliance Management of MS licenced facilities

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Who we are, mission and vision



We are the Medicines and Healthcare products Regulatory Agency (MHRA).

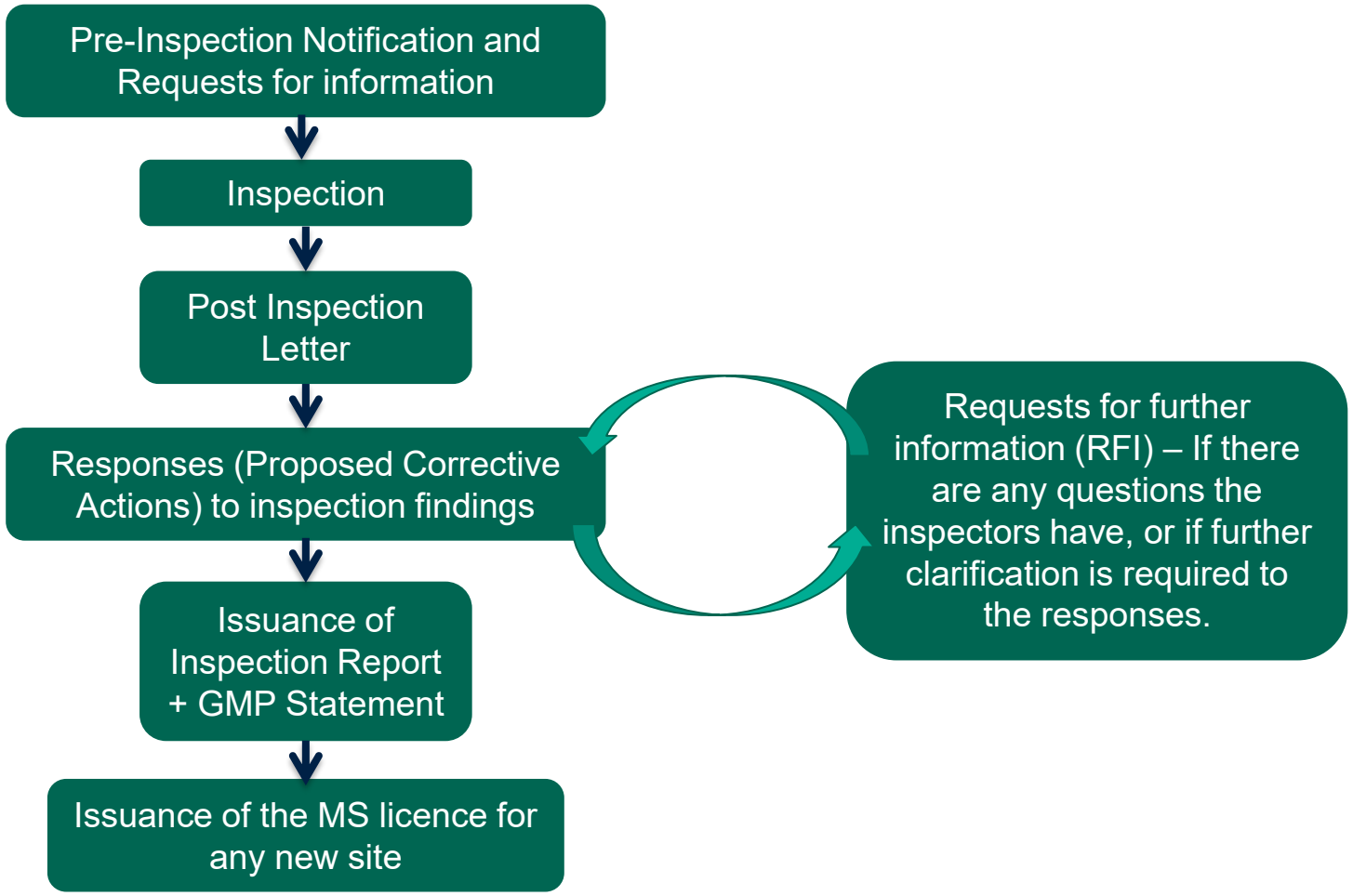
We improve and protect the health of millions of people every day by making sure healthcare products in the UK **meet the highest standards** and are safe to use.

We are the UK regulator of medicines, medical devices and blood components for transfusion. We are responsible for making sure these products meet set standards for safety, quality and efficacy.

Mission: To protect and improve public health.

Vision: To be a world-leading, enabling sovereign regulator, protecting public health through excellence in regulation and science and delivering the right outcomes for patients.

Inspection Process



Successful Inspection Criteria

- **Transparency** with MHRA inspectors throughout the inspection process.
- **Demonstrating** (vs describing) compliance with Good Manufacturing Practice.
    - Focus on Aseptic controls (EU GMP Annex 1)
    - Focus on the requirements outlined in the MHRA Guidance for Specials Manufacturers
- **Record and Data Review** i.e. Prove it works
    - Training linked to SOP's
    - Calibration and maintenance records
    - Validation and verification records – process and personnel
- **Coherent** & **specific** responses to inspection findings.

GMP Inspection outcomes



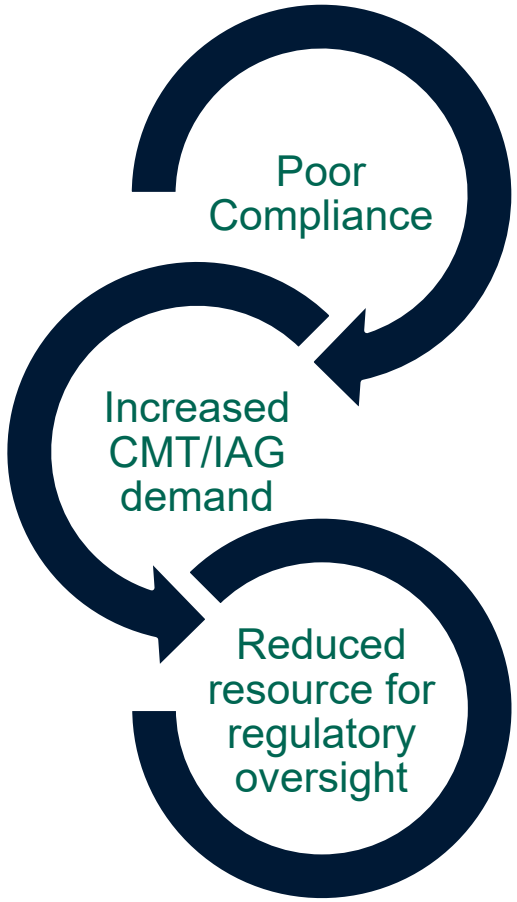
The norm

Actions after the inspection:

After the inspection closing meeting, you will receive a post inspection letter confirming any deficiencies found.

You must respond to the inspector by email to confirm the proposed corrective actions and dates for when these actions will be completed. The inspector will review your response. If they accept it, you will receive a **GMP or GDP certificate** with your inspection report. An unacceptable response may lead to *compliance escalation* if further requests for information are unsatisfactory.

Upstream intervention



Poor compliance results in significant downstream impact on patients, the supply chain and the resources of the regulator (CMT, IAG).

By increasing our upstream engagement across the product lifecycle with stakeholders we can inform and educate and reduce the cost of poor compliance

Inspection Action Group – referrals after Critical Findings

IAG1 considers issues related to good manufacturing practice (“GMP”)

Possible actions as a result of a referral are:

- refusal to grant or vary a licence, proposal to suspend licence for a stated period, notification of immediate suspension of a licence, proposal to revoke or vary the licence
- removal of named individuals from a licence, requests for information issued to named individuals on a licence, referral of a named individual on a licence to their professional body
- a meeting with the agency, statement of GMP non-compliance, conditioned GMP Certificate
- compliance monitor oversight, increased inspection frequency/follow-up/triggered inspections

In all cases, an action could result in the withdrawal of a product from the market. This action is overseen by the Defective Medicines Reporting Centre (DMRC) at MHRA rather than IAG.

Compliance Management Escalation

Compliance Management Team (CMT)

CMT is also a non-statutory process and is managed within the GMP Inspectorate by senior and expert inspectors, operations and unit managers rather than the wider multi-disciplinary team of IAG.

Initially devised back in 2013, the compliance management approach was established to point out the 'compliance icebergs' on the horizon, particularly those that companies were failing to see. This can create time to change course and stop a 'titanic' issue occurring.



https://mhrainspectorate.blog.gov.uk/2017/02/06/overview-of-compliance-management-escalation-processes-used-by-the-gmp-inspectorate/

MHRA goal for compliance oversight

- Support and encourage poorly performing sites into an appropriate level of compliance
- Looking for sites to actively and proactively engage in resolving issues, ensuring immediate and ongoing improvements

- Understanding of difficulties, especially at NHS sites

- Looking for long term viability of Manufacturing facilities, to support long term provision of medicines to patients
  - Via the physical facility
  - Via the appropriate staffing levels with the appropriate GMP expertise

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