



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Guidance for applicants/MAHs involved in GMP inspections coordinated by EMA

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1. GMP Inspections

These inspections are requested by the **Committee** for Medicinal Products for Human Use and/or the Committee for Medicinal Products for Veterinary Use in order to verify compliance with Good Manufacturing Practice of sites responsible for the manufacture of centrally authorised products.

The details of each of the inspections adopted by the Committee(s), including the contact details of the persons in the inspection services who will be involved can be found in the [IRIS Industry portal](#). Please let us know immediately if any of the information given has changed or is incorrect and if there are any problems with the proposed timing. The inspectors will contact you to finalise the dates and detailed arrangements.

1.1. Inspection Fees

In accordance with [Council Regulation \(EC\) No. 297/95](#), as amended, inspection fees are payable in connection with this inspection and an invoice for this will be sent to you by the EMA. For more information, please consult the [Fees website](#). In addition to the inspection fees you are required by the same regulation to meet the travel and accommodation costs of the inspector(s) (and, if present, the expert), for sites located outside the EU/EEA. These expenses are to be paid directly by the applicant/MAH to the inspectors' authorities and according to the policy/requirements of the inspectors' authorities which may vary amongst the Member States. The applicant/MAH is kindly requested to assist with any travel arrangements following discussion and agreement with the reporting inspector.

In the case of a **small and medium-sized enterprise (SME)**, you may be eligible for a fee reduction. Further information is available on the [EMA website](#).

Please provide via the [IRIS Industry portal](#) a purchase order (PO) reference number within 10 working days of inspection announcement. If your company does not have any internal purchase order number, please put N/A in the IRIS Industry portal. Purchase order information will be quoted on the invoice issued for the inspection carried out.

Please note that the EMA will not accept delays on payments based on missing purchase order (PO) reference number information.

If you need any further information about the procedure to be followed for the inspections, please do not hesitate to contact the EMA Inspection Coordinator through the case in IRIS.

1.2. Legal basis and References

- Articles 8(2), 33(2), 19(3) and 44(3) of Regulation (EC) 726/2004
- Article 111(1) of Directive 2001/83/EC
- Article 80(1) of Directive 2001/82/EC