Human Medicines Division
EMA/68213/2024

Business process description

Title: Inspection coordination		
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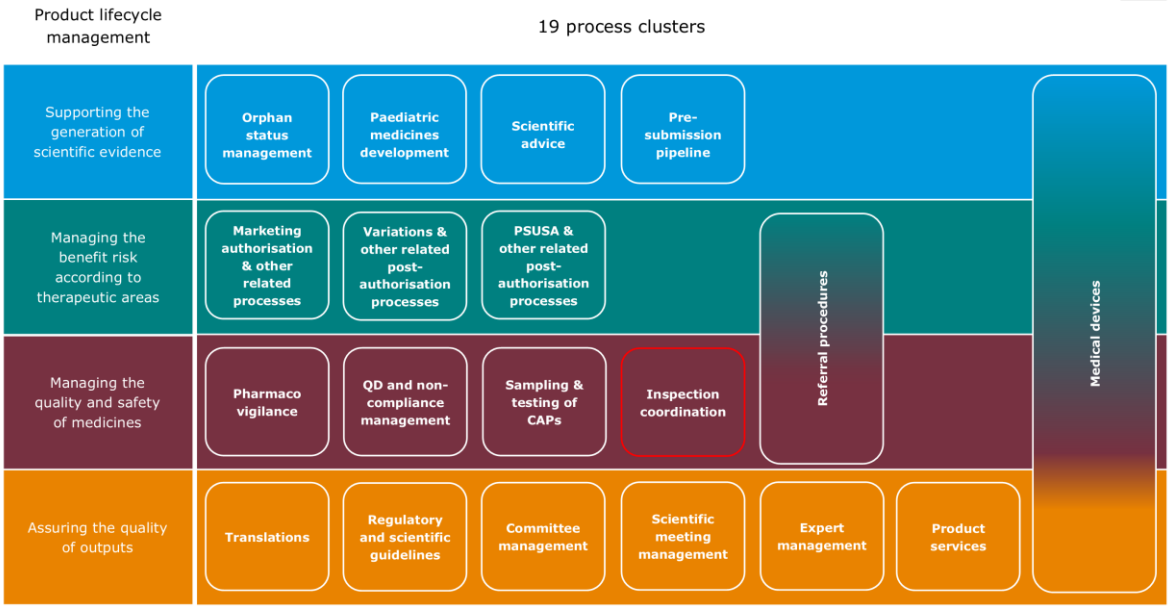
1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for inspection coordination, which verifies that organisations involved in the development, manufacturing and marketing of medicines are compliant with the relevant standards set out in the EU legislation and guidelines on pharmaceuticals.

This process is part of the Human Medicines Division's process map (image below) which provides a high-level overview of the 19 process clusters within the operating model of the Human Medicines Division.

Human Medicines Division process map
Managing the product lifecycle and medical devices



Inspection coordination process:

It describes the following sub-processes:

- Co-ordination of inspections in the context of plasma master file certification
- Co-ordination of GCP inspections (human and veterinary medicines)
- Co-ordination of pharmacovigilance inspections (human and veterinary medicines)
- Co-ordination of GMP inspections (human and veterinary medicines)
- Co-ordination of GLP inspections (human and veterinary medicines)

These inspections can be requested:

- in the pre-authorisation phase, in relation to marketing authorisation applications, or
- in the post-authorisation phase, in relation to routine re-inspections, variations, line extensions, specific obligations/follow-up measures, safety updates, suspicion of GxP non-compliance, quality defects, etc.

2. Changes since last revision

New business process description

3. Related documents

Procedure documents:

- Procedure for coordinating GCP inspections requested by the CHMP (EMA/INS/GCP/55482/2013)
- Procedure for reporting of GCP inspections requested by the Committee for Medicinal Products for Human Use (CHMP) (EMA/INS/GCP/158549/2016 Rev. 1)
- Compilation of Union procedures on inspections and exchange of information | European Medicines Agency (EMA) (europa.eu)
- Union procedure on the coordination of EU veterinary pharmacovigilance inspections (EMA/INS/PhV/716593/2021 Rev. 1)
- Union procedure on the preparation, conduct and reporting of EU veterinary pharmacovigilance inspections (EMA/INS/PhV/604648/2022 Rev. 1)
- Union procedure on the coordination of EU human pharmacovigilance inspections (EMA/INS/PhV/192234/2014)
- Union procedure on the preparation, conduct and reporting of EU human pharmacovigilance inspections (EMA/INS/PhV/192230/2014)

Guidance documents:

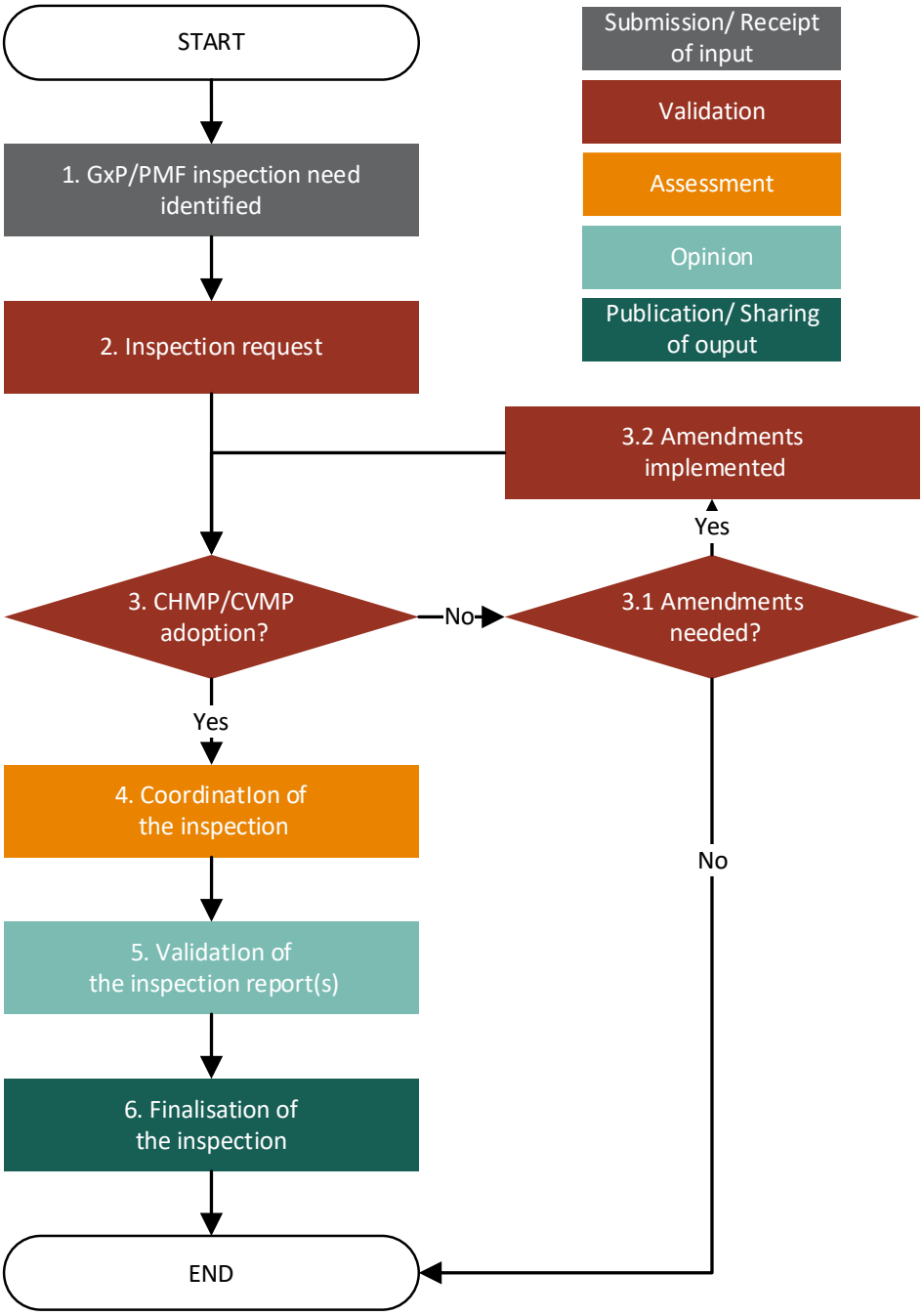
- Guidance for applicants/MAHs involved in GMP, GCP and GVP inspections coordinated by EMA (EMA/274221/2021)
- Guideline on Veterinary Good Pharmacovigilance Practices (VGVP) Module: Controls and pharmacovigilance Inspections (EMA/328998/2021)

- Guideline on good pharmacovigilance practices (GVP) Module III – Pharmacovigilance inspections (Rev 1) (EMA/119871/2012 Rev 1*)

4. Abbreviations/Definitions

CAPs	Centrally authorised products
CHMP	Committee for Human Medicinal Products
CVMP	Committee for Veterinary Medicinal Products
EMA	European Medicines Agency
EU	European Union
GxP	Good practice standards comprising: Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Good Vigilance Practice (GVP)
MAH	Marketing authorisation holder
MS	Member States
NCA	National competent authority
PhV	Pharmacovigilance
PhVWP	Pharmacovigilance Working Party
PMF	Plasma master file
PSUSA	Periodic safety update report single assessment
QD	Quality defect
QPPV	Qualified Person Responsible for Pharmacovigilance
VGVP	Veterinary Good Pharmacovigilance Practices

5. Process map(s)



6. Procedure

Step	Description
1.	**GxP/PMF inspection need identified:** • as a result of a regulatory procedure (e.g. initial marketing authorisation applications, variations etc.) • upon request of the PMF holder/NCA • based on GMP/PhV re-inspection programmes • as a result of a suspicion of GxP non-compliance (GxP for-cause inspections)
2.	**Inspection request** • Create an inspection request
3.	**CHMP/CVMP adoption?** Inspection requests for human medicines are sent to CHMP and for veterinary medicines to CVMP Is the inspection request adopted? • If yes, go to step 4 • If no, go to step 3.1
3.1	**Amendments needed?** Is CHMP/CVMP requesting changes to the inspection request? • If yes, go to step 3.2 • If no, the inspection is not conducted, and the process ends
3.2	**Amendments implemented** • After implementing the amendments, re-send the inspection request to CHMP/CVMP for adoption (go to step 3)
4.	**Coordination of the inspection** • Notify applicant/MAH/PMF holder/NCA/inspectorates of the inspection • Inspections are conducted by GxP/PMF inspectors from EU MSs • Before the start of the inspection, EMA performs the evaluation of the declaration of interest of the appointed inspectors/experts
5.	**Validation of the inspection report(s)** and the relevant documents provided by the inspectors
6.	**Finalisation of the inspection** Depending on the type of inspection, relevant parties are informed by EMA: • **GCP**: rapporteur, co-rapporteur, applicant/sponsor, CHMP/CVMP, involved inspectorates • **PhV**: rapporteur, co-rapporteur, MAH/QPPV, CHMP, CVMP/PhVWP, involved inspectorates • **GLP**: rapporteur, co-rapporteur, applicant, CHMP, involved inspectorates • **GMP**: rapporteur, co-rapporteur, MAH, involved inspectorates • **PMF**: PMF holder informed directly by involved inspectorate(s)