HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Compliance Management Process

QP Forum, Trinity College Dublin, 12th May 2026

Ciara Turley

Compliance Management

- Outcome of GMP inspections
  - GMP Certificate / Statement of Non Compliance

- HPRA has an internal review process where there is an adverse inspection outcome and there is concern about ongoing GMP compliance
- Compliance Management – escalation of compliance concerns to authorisation holders for immediate attention if regulatory action is to be avoided.
- Reference: Compilation of Union Procedures: Procedure for compliance management

EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL
Health systems, medical products and innovation
Medical products: quality, safety, innovation

EUROPEAN MEDICINES AGENCY
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Procedure for compliance management

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Title	**Procedure for compliance management**
Date of adoption	May 2023
Date of entry into force	1 January 2024
Supersedes	Version adopted 21 September 2021
Reason for revision	Modifications were introduced as a result of the entry into application of Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC and Regulation (EU) 2019/5 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
Notes	Not applicable
Last publication date:	1 August 2024
Document version	1

Compliance Management

- Compliance management is appropriate in situations where increased frequency of inspections is considered not to be effective in achieving compliance improvements within a satisfactory time period.
- Communication of the national competent authority's concerns (HPRA) to the authorisation holder senior management

- Process includes non-inspection monitoring measures (e.g. progress reports / compliance reports) and monitoring via inspections
  - Reporting CAPA implementation progress
  - Reporting of any adverse GMP compliance indicators from the market place

GMP Certificate will identify that the site is under Compliance Management and may have shortened validity period

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification

Clarifying remarks (for public users)

This GMP certificate is issued with administrative action(s) described within the procedure for compliance management in the Compilation of Union Procedures. The HPRA does not routinely issue signed hard copy GMP certificates. Authenticity of GMP certification can be verified on the EudraGMDP database.

2026-04-24

Name and signature of the authorised person of the Competent Authority of Ireland

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Compliance Management

- Re-inspection will be required to verify acceptable GMP compliance in order to exit from Compliance Management

- Inspections may be unannounced

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Questions