MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

Mutual recognition: basic aspects and mechanism. GMP certificates

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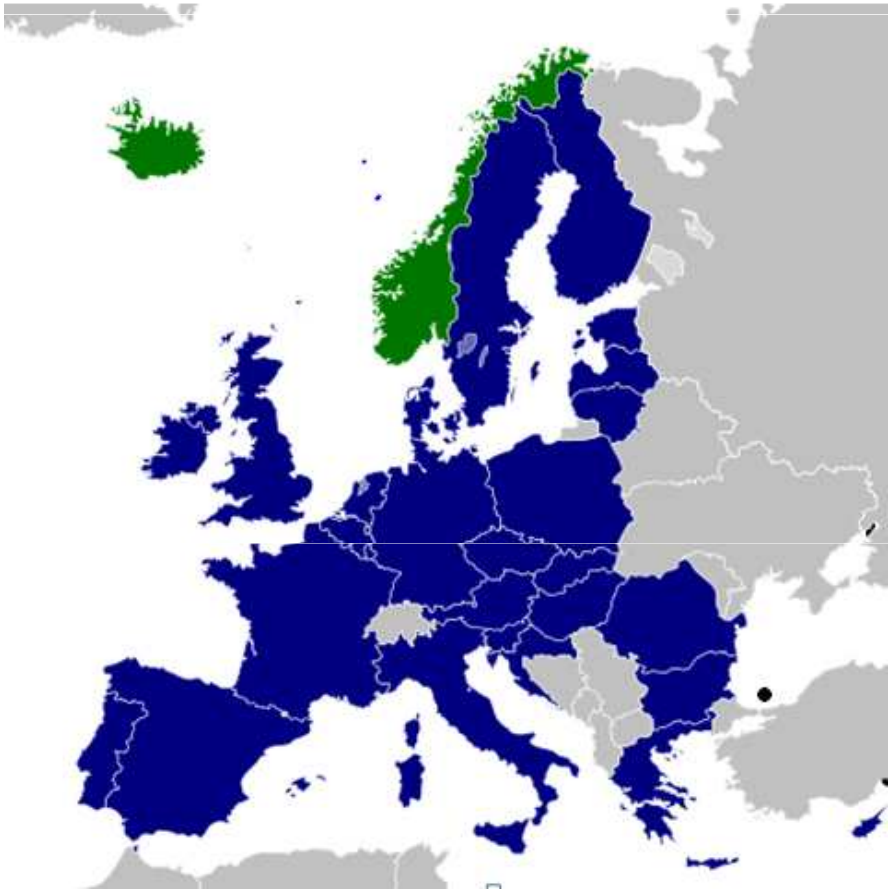
The EU network of medicines agencies

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



- 31 countries:
  - 28 EU MMSS
  - + 3 Members of the European Economic Area (EEA)
- 44 medicines agencies (human and vet)
- UE + EEA population
  > than 500 millions

Basic elements for the cooperation between NCAs: The EU network of medicines agencies

- Common legislation and GMP Standards
  https://ec.europa.eu/health/human-use/quality_en
- Common procedures: compilation of community procedures
  http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf
- Common database on authorizations and certificates
  http://eudragmdp.ema.europa.eu/inspections/displayWelcome.do
- Internal EU audit programme: Joint Audit Program (JAP)
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/joint_audit_programme.jsp&mid=WC0b01ac058006e06f

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Joint Audit Program (JAP)

- **Objective**: to achieve, maintain and verify equivalence and practical application of GMP standards by national inspectorates agencies across the EEA countries and MRA partners
- National inspectorates are audited by **qualified auditors** (experienced GMP inspectors) from several countries
- Evaluation guide **agreed with PIC/S**
- Tool for international collaboration: to **preserve confidence** in the equivalence of GMP systems to all EEA countries and MRA partners
- Joint audits are expected to lead to an **improvement** of the assessed authorities and allow the possibility that national auditors can transfer experiences gained during the audits to their national inspectorates
- The Joint Audit Programme also **contributes to the training** of inspectors

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Agreements between the EU and third countries

- Cooperation agreements allow EU authorities and their counterparts to:
  - rely on each other's GMP inspection system;
  - share information on inspections and quality defects;
  - waive batch testing of products on import into their territories;
- They aim to facilitate **market access** and encourage greater **international harmonisation** of compliance standards while protecting consumer safety
- They also facilitate trade in pharmaceuticals because they **reduce costs for manufacturers** by reducing the number of inspections taking place at facilities and waiving re-testing of their products upon importation
- Basic content is similar but the **scope varies** between the different current agreements
- The agreements are signed between **all EU MMSS and a third country**
- Detailed information in:

  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001843.jsp&mid=WC0b01ac058005f8ac

Current EU agreements

- Mutual recognition agreements (MRA)
  - Australia (1999) 
  - Canada (2003) 
  - Japan (2004) 
  - New Zealand (1999) 
  - Switzerland (2002) 
- Agreement on Conformity Assessment and Acceptance (ACCA)
  - Israel (2013) 
- Mutual recognition of inspections (MRI)
  - United States of America (2017, transitional period till 2019) 

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Spanish experience in JAP audits

- As **auditor**:
  - AEMPS GMP inspectors have participated in the JAP assessment of 6 countries systems in the last 2 years (in and outside the EU)

- As **auditee**:
  - **Audit team**: inspectors from United Kingdon (MHRA), Eslovenia (JAZMP), Canadá (Health Canada) and 3 observers from United States of America (FDA)
  - **Preparation**: a coordination group for the process was set in AEMPS with a relevant role for our Technical Inspection Committee
  - Answers to the checklist and relevant procedures were provided to the auditor team prior to the one week **audit visit in November 2016**:
    - On-site evaluation at Inspectorate
    - On-site evaluation at Laboratory
    - 2 observed inspections
  - JAP report received in January 2017 / AEMPS replies sent in January 2017/ **Final positive report in February 2017**

GMP certificates

- Essential document **proof** of GMP compliance
- **After each GMP inspection** a certificate or a non-complicance statement must be issued
- EU **certificates content** is defined in the Compilation of Community Procedures and includes:
  - Name of the NCA isssuing it
  - Identification of the inspected site
  - Applicable legislation
  - Date of the inspection visit
  - Statement of compliance with GMP requirements
  - Validity period: 3 years but might be extended or reduced
  - Manufacturing activities to which it applies
- EU certificates may be consulted in **EUDRAGMDP database**: http://eudragmdp.ema.europa.eu/inspections/displayWelcome.do

Спаси́бо!