VERIFICATION OF GLP COMPLIANCE

AD HOC MEETING WITH GMO INDUSTRY REPRESENTATIVES 30 OCTOBER 2025

FRONT DESK & WORKFORCE PLANNING UNIT

efsa
EUROPEAN FOOD SAFETY AUTHORITY

GOOD LABORATORY PRACTICE (GLP) REQUIREMENTS

GMO studies (Article 4 of IR 503/2013):

- GLP for toxicological studies
- GLP or ISO for studies other than toxicological studies

- Information on the acceptance of GLP studies and how to verify the GLP status of a test facility is available on EFSA's website and in the GMO Administrative guidance documents
- Website updated to better clarify the concept of GLP compliant test facilities. Administrative guidance will be updated

GLP COMPLIANCE CHECK BY EFSA

- Verification of GLP status of studies in accordance with OECD No. 20 during completeness check (CC)
  - ➢ This includes verification of GLP status of test facility (TF) in OECD Annual Overviews: relevant inspection date (3-year interval) and area of expertise
- Study audit request during CC in case GLP status of TF is to be confirmed by national GLP Monitoring Authority (through an EU GLP MA when the TF is located outside the EU)
  - ➢ Study audits are not intended to exclude valid studies, but rather to receive confirmation from the national GLP MA on their GLP status

EFSA GLP study audits

EFSA can ask a GLP monitoring authority to carry out a GLP study audit to verify the GLP status of submitted studies under the relevant procedure. This may be either in the context of EFSA's annual audit programme, or on ad hoc basis when we identify specific GLP-related concerns.

- ❑ EFSA SOP_022
- ❑ OECD No. 20 (Guidance for receiving authorities)