Ensuring the reliability of data

Internal and external monitoring help to ensure the reliability of data collected under GLP.

INTERNAL

INTERNAL INSPECTIONS

Conducted by internal Quality Assurance (QA) Unit and QA auditor

Each study can be divided into critical phases, e.g. application, sampling, processing, analysis. Together with the study plan/ protocol and the report, these phases form the basis for reviews. Although not all of the critical phases are audited by QA in every study, a review is carried out regularly by QA, so that high quality and traceability of the studies is guaranteed.

The role of a QA inspector: assuring studies are performed in compliance with GLP regulations

The independence of QA is required by law and includes:

- Organizational independence from personnel engaged in study conduct
- No other responsibilities in the study conduct or data generation

EXTERNAL

REGULATORY AGENCIES AND MONITORING AUTHORITIES

Each country has a Regulatory Agency or Monitoring Authority which conducts inspections or check ins during or after the product submission process. These inspections or check ins are to assure that the GLP facility is compliant with the Replace by country`s specific GLP requirements. These are generally random and unscheduled and provide a close look at one or more of the GLP facilities studies to the Regulatory Agency or Monitoring Authority.

An inspection certificate may or may not be provided depending on the specific countries Regulatory Agency or Monitoring Authorities process.

For example, in the European Union, the European Food Safety Authority (EFSA) follows the following process:

Safety is assessed by a weight of evidence approach which evaluates a battery of studies, not a single study alone. EFSA utilizes a mutual monitoring process, so the submission of a new substance can involve:

What happens if monitoring authorities have found mistakes or any violation against the GLP regulations?

Hover over the different elements to learn more.