swissmedic
Swiss Agency for Therapeutic Products

News from the Swiss GLP Monitoring Authorities

Dr. Elisabeth Klenke
GLP Compliance Monitoring Unit
Swissmedic

Newsletter 2012

- ✓ **Update of „Interpretationen“**
  - ✓ Master Schedule
  - ✓ Signatures on the final report
- ✓ **Revision of GLP Monitoring Programme**
  - ✓ Deviations from GLP compliance
  - ✓ Number of studies for enrolment etc.

Master Schedule (MS) I

- ✓ Requirements regarding the MS are not outlined in detail in the OGLP. The Swiss GLP Compliance Monitoring Units therefore listed minimal requirements.
- ✓ Similar standards are applicable to short and long-term studies.
- ✓ The MS is considered to be *i.a.* a planning tool, which needs constant updating, but is not required to be completed retrospectively.
- ✓ It is recommended to identify multisite studies in the MS of the test facility.
- ✓ Cancelled studies should be identified as such.

Master Schedule II

- ✓ Study number
- ✓ Phase number
- ✓ Study director
- ✓ Principal Investigator
- ✓ Test item
- ✓ Type of study
- ✓ Start of study / phase
- ✓ End of study/ phase
- ✓ Archiving date
- ✓ GLP / non-GLP study (yes/no)

Master Schedule III

- ✓ for **multi site studies**: the information should be available in the MS of the test site. An entry regarding a multi site study is required for the test facility as well as for all concerned test sites.
- ✓ authorities recommend to include **all studies** to estimate the total workload of the test facility. However, if only a low percentage (e.g., 5 %) of GLP vs. non GLP studies is performed, a master schedule only for GLP studies (or in case of multi-site studies: study phases) and validation studies performed according to GLP should be established.

Newsletter 2012

- ✓ **Update of „Interpretationen“**
  - ✓ Master Schedule
  - ✓ **Signatures on the final report**
- ✓ **Revision of GLP Monitoring Programme**
  - ✓ Deviations from GLP compliance
  - ✓ Number of studies…

Signatures on the final report I

- ✓ Management should ensure that all final reports for which GLP compliance is claimed are audited by QA personnel.
- ✓ This audit should be conducted at the final draft stage, when all raw data have been gathered and no more major changes are expected.

Signatures on the final report II

- ✓ **After the following checks, the QA representative signs the QA statement:**
  - ✓ all issues raised in the QA audit have been appropriately addressed in the final report,
  - ✓ all agreed actions have been completed,
  - ✓ no changes to the report have been made which would require a further audit and
  - ✓ the Study Director’s claim to GLP compliance can be supported.

Signatures on the final report III

- ✓ The Study Director carries the overall responsibility and confirms with his signature that a signed QA statement is available in the report.
- ✓ It is recommended that finalisation of a study report by the Study Director should not take longer than 5 business days after the QA statement has been signed.
- ✓ Any additions to a final report (e.g. addition of QA statement) would require an amendment to report.

Newsletter 2012

- ✓ **Update of „Interpretationen“**
  - ✓ Master Schedule
  - ✓ Signatures on the final report
- ✓ **Revision of GLP Monitoring Programme**
  - ✓ **Deviations from GLP compliance**
  - ✓ Number of studies…

Deviations from GLP Compliance

Categories

- ✓ **major deviations** are deficiencies observed in the test facility or part thereof, or in one or several studies, which affect or may affect the GLP compliance of the test facility itself or the validity of the study (studies)
- ✓ **minor deviations** are deficiencies observed in the test facility or part thereof, or in one or several studies, which do not affect the GLP compliance of the test facility itself or the validity of the study (studies)
- ✓ Further **observations** might result in recommendations, but are not considered to be a deviation.

Major deviations I

- ✓ **No corrective action** can be taken (i.e. in the case of a study audit) – negative decision:
- ✓ inspectors provide a draft report to the test facility with their observed major deviations and a negative conclusion concerning GLP compliance
- ✓ report is finalized after considering and integrating the statement from the test facility
- ✓ Notification Authority will emit a negative decision.

Major deviations II

- ✓ **Corrective actions** can be taken – positive decision:
- ✓ Request for corrective actions is described as **condition(s)** in the inspection or audit report.
- ✓ Proposed conditions, if already fulfilled according to the statement from the test facility on the draft inspection or audit report, will not be mentioned in the positive decision of GLP compliance emitted by the Notification Authority.

Major deviations III

- ✓ If the competent GLP authority considers the submitted documents to be incomplete or inaccurate, it shall inform the test facility within 14 days.
- ✓ A test facility or study is only GLP compliant, once the condition(s) stipulated in the decision are fulfilled in the due time and quality. Otherwise the status is changed to “not in compliance” automatically (no new decision required).

Minor deviations

- ✓ Request for corrective action is mentioned as **stipulation** in the inspection or audit report.
- ✓ Proposed stipulations, if already fulfilled according to the statement from the test facility on the draft inspection or audit report, will not be mentioned in the positive decision of GLP compliance emitted by the Notification Authority.
- ✓ Stipulation(s) need to be corrected in due time. If necessary a new decision is issued for enforcement.

Other observations

- ✓ No corrective action is required for **recommendations**, however the test facility can inform on measures taken to respond the observation.

Newsletter 2012

- ✓ **Update of „Interpretationen“**
  - ✓ Master Schedule
  - ✓ Signatures on the final report
- ✓ **Revision of GLP Monitoring Programme**
  - ✓ Deviations from GLP compliance
  - ✓ **Number of studies…**

Number of GLP studies I

- ✓ **Enrolment in GLP Compliance Monitoring Programme**
  - ✓ The prospective GLP test facility should already dispose of good experience in GLP studies, having completed two studies per area of expertise.
  - ✓ Exceptions to this rule might be granted by the authorities.
- ✓ **Routine inspections**
  - ✓ One study per area of expertise, but at least two studies per test facility have to be completed to remain in the programme.

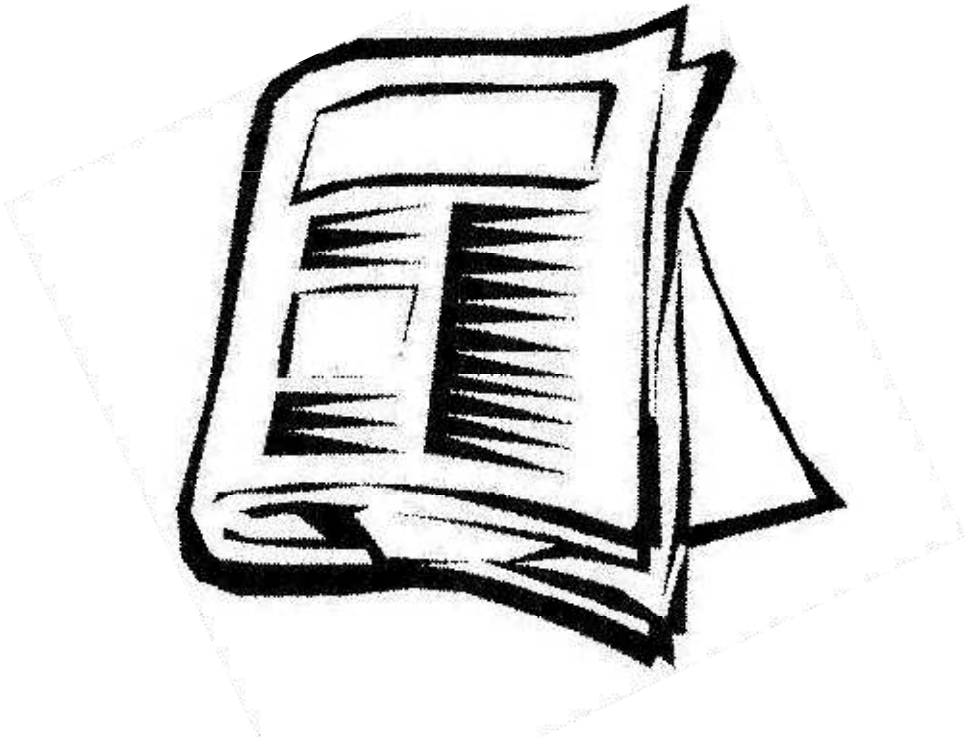
Number of GLP studies required II

- ✓ **Routine inspections**
  - ✓ One study per area of expertise, but at least two studies per test facility have to be completed between two consecutive routine inspections.
  - ✓ If this is not the case the test facility will be informed on the minimum requirements to remain in the GLP register/list via a condition. If this condition is not fulfilled, the test facility is removed from the GLP Compliance Monitoring Programme or the area of expertise is not confirmed. Exceptions to this rule might be granted by the authorities.

Updated after SPAQA meeting

swissmedic

The Newsletter will be sent out by the end of the year!



Thank you for your attention!

Questions?

swissmedic