GLP Roundtable 2014

Guidance on the GLP Requirements for Peer Review of Histopathology Advisory Document

swissmedic

Dr. Elisabeth Klenke, Head Preclinical Review and GLP Monitoring Compliance Unit

Swissmedic • Swiss Agency for Therapeutic Products • Hallerstrasse 7 • 3000 Berne 9 • Switzerland • www.swissmedic.ch

swissmedic

History

NEWS

Peer Review Advisory Document

The OECD has now issued the long awaited Advisory document on Peer Review.

2010 24th OECD WG meeting on GLP
drafting group: lead UK, member: CH and others
Input from key stakeholders

2014 28th OECD WG meeting on GLP
04/2014 endorsement, 09/2014 publication

swissmedic

Background I/II

- Pathological assessment of histopathological slides
  - Key endpoint based on expert opinion

- Peer review: to ensure quality and accuracy of interpretation
  - Could change outcome of a study
  - Receiving authorities have expectations that peer review is performed

swissmedic

Background II/II

- No GLP requirement for peer review
  - Scientific value – non GLP experts
- guidance to pathologists, test facility management, study directors and quality assurance personnel on how the peer review of histopathology should be planned, managed, documented and reported in order to meet GLP expectations and requirements.

swissmedic

GLP requirements

- should be clearly described in the study plan or subsequent study plan amendments or in an SOP
  - includes: planning, managing, documenting, reporting, timing

- Sufficient information to allow reconstruction of how tissues will be selected for peer review whilst allowing sufficient flexibility to react to unexpected pathology findings

swissmedic

Responsibilities

Study director	ultimate responsibility
Peer review pathologist	contributing scientist: interpreting but not generating data

Study file

- Should contain:
  - Details on conduct
    - *Who* identity and affiliation of peer reviewing pathologist
    - *What* identity of selected tissues
    - *When* timing
  - All correspondence used for peer review (between the sponsor and representatives of the test facility and the peer review pathologist)

→ Raw data
→ Slides and corresponding blocks

} necessary for reconstruction

swissmedic

Not in study file

- Notes made by the peer review pathologist which are used to record observations during the histopathological examination of individual slides

swissmedic

Scenario 1: no agreement

- between pathologist and peer review pathologist
  - facility's SOPs: clear, transparent and unbiased process should be implemented to resolve their differences.
    - Involvement of independent experts or panel of experts
  - final report: description of how differences of interpretation were handled and changes made to the study pathologist's original interpretation

swissmedic

Scenario 1: agreement

- between pathologist and peer review pathologist
  - Final report: statement that it was conducted and that the pathology report presents the agreed findings
  - no requirement for the peer reviewing pathologist to sign the pathology report or the final report

swissmedic

Non GLP peer review pathologist

- pathology peer review in a non GLP facility it should be justified and recorded within the study plan and final report (SD statement)
- alternative: perform peer review at the GLP test facility that conducted the study
  - no transfer of slides
  - perform peer review under the umbrella of an established GLP quality system
    - expectation: peer reviewing pathologist would receive an appropriate level of training in the relevant facility procedures.

swissmedic

Key elements to consider for study director

- Evidence of experience/expertise of the reviewing pathologist.
- A review of the facility's SOPs or a documented agreement that the peer reviewing pathologist will use the test facilities SOPs and procedures.
- Chain of custody of samples and associated paperwork.
- Security of samples and documents whilst at the peer reviewing pathologists facility
- Validation of any computer applications (if applicable).
- Adequate quality assurance activities which may include an audit of the premises and equipment used by the reviewing pathologist.

swissmedic

Thank you!