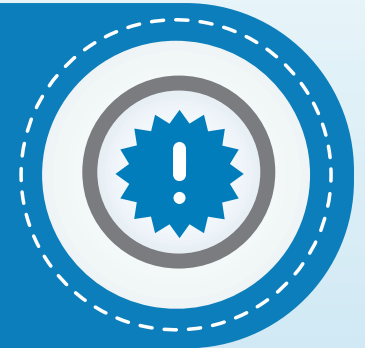


Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers

Final Guidance for Industry

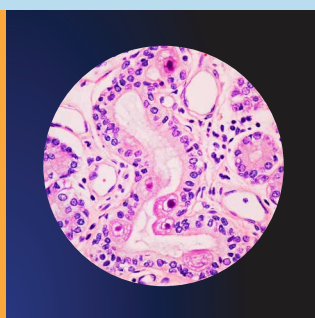
What Is Covered in This Guidance?

The final guidance Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers provides information to sponsors and nonclinical laboratory staff regarding the management and conduct of pathology peer review performed during good laboratory practice (GLP)-compliant toxicology studies.



What Is Pathology Peer Review, and Why Is It Performed?

Pathology peer review is the process by which the findings of the pathologist assigned to a study (study pathologist) are subjected to review by another pathologist (peer-review pathologist) or group of pathologists (peer-review pathologists). While pathology peer review is not required by the GLP regulations, it can be valuable, particularly when unique or unexpected findings are noted or when the peer-review pathologist has a particular expertise with a class of compounds.



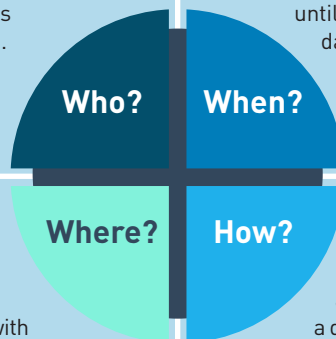
The peer-review pathologist should have a combination of appropriate education, training, and experience to be qualified to render opinions on the study pathologist's histological descriptions.

Pathology peer review can occur before or after finalization of the study pathologist's report. The draft pathology report is subject to change until the report is signed and dated by the study pathologist.



A pathology peer review should be planned, conducted, documented, and reported in accordance with established procedures. It is preferable that pathology peer review be performed at a GLP-compliant testing site.

A standard operating procedure and GLP study protocol (or protocol amendments) should include a description of the peer-review procedure, including the selected target tissues, dose groups, number of specimens, blinding procedures, and the process for resolving interpretive differences between the study pathologist and the peer-review pathologist.



Guidance Snapshots are a communication tool and are not a substitute for the guidance document.

To learn more about pathology peer review in nonclinical toxicology studies, read the guidance:

<https://www.fda.gov/media/129533/download>

Background About the Guidance

This guidance finalizes the draft guidance published in July 2019 titled Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers. Currently, documentation practices during pathology peer review are not clearly defined and vary among nonclinical testing facilities. In addition, pathology peer review is not specifically addressed in the GLP regulations. This question-and-answer document is intended to clarify FDA's recommendations concerning the management, conduct, and documentation of pathology peer review. Casual discussions, opinion exchange, and mentoring among pathologists are not covered by this guidance.



Drug Development Timeline – When to Apply the Guidance Recommendations



During Nonclinical Toxicology Studies:

This question-and-answer document is intended to clarify FDA's recommendations concerning the management, conduct, and documentation of pathology peer review that occurs during a nonclinical toxicology study under GLP (referred to as a GLP toxicology study).

Guidance Recap Podcast – Hear Highlights Straight From FDA Staff

Speaker: Lynda Lanning, DVM, DABT, Toxicologic Pathologist in the Center for Drug Evaluation and Research's Office of Study Integrity and Surveillance



Click here to listen



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To see additional Guidance Snapshots, check out the pilot program:

<https://www.fda.gov/drugs/guidances-drugs/guidance-snapshot-pilot>