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## **GLP-like Evaluation Matrix**

Self-Assessment for Audit-Ready  
Preclinical Reports






# GLP-like Evaluation Matrix

## Self-Assessment for Audit-Ready Preclinical Reports

Criterion & Research Question	Rating
<p><b>01 Research question, endpoints, and release criteria</b> Have the research question, the endpoints, and the release criteria been documented in writing before the first measurement was taken?</p>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<p><b>02 Study protocol with version management</b> Is there a plan that was dated and signed prior to the start of the study, and are protocol changes, including an assessment of their regulatory impact, being fully documented?</p>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<p><b>03 Raw data definition according to ALCOA+</b> Is primary data clearly defined, and does it meet the ALCOA+ criteria (accountable, legible, current, original, and accurate)?</p>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<p><b>04 Test article &amp; complete sample and material chain?</b> Does the test sample (batch, manufacturing, cleaning, sterilization) correspond to the final product, and is the sample history fully and traceably documented?</p>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<p><b>05 SOPs, calibration &amp; system validation</b> Are critical processes controlled by SOPs, and are all devices calibrated and software-based systems (computer validation, CSV) validated?</p>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<p><b>06 Independent quality assurance (documentation of audit steps)</b> Is documented evidence of the test steps available showing who independently reviewed the study, when, and what the results were?</p>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<p><b>07 Study Director, roles &amp; training records</b> Are responsibilities, including competencies, clearly defined, and are current, task-specific training records (SOP training) available for all involved personnel?</p>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<p><b>08 Complete documentation of deviations &amp; CAPA process</b> Are deviations promptly recorded and assessed promptly, and are any critical or relevant resulting CAPAs assessed, tracked, and, where necessary, closed with regard to regulatory submission?</p>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<p><b>09 Statistical validity &amp; data analysis</b> Were the evaluation methods (including the handling of statistical outliers) planned in advance, and can the path from the raw data value to the reported result reconstructed without gaps?</p>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<p><b>10 Final report, independent quality review &amp; archiving</b> Is there a traceable documented, independent quality review of the report, and is access-restricted, long-term archiving of all relevant original documents ensured?</p>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

### Rating Logic (Traffic Light System)

-  **Green:** Fully available and documented.
-  **Yellow:** Available, but incomplete or out of date.
-  **Red:** Completely missing.



# GLP-like Evaluation Matrix

Self-Check for Audit-Ready Preclinical Reports

## Risk Analysis & Recommended Actions

### Critical

Three or more red dots are a strong indication that the report's defensibility in regulatory reviews, audits, or submissions is significantly limited—regardless of the study's scientific quality.

### Warning

Clusters of yellow dots indicate systemic weaknesses in the chain of evidence, which may lead to critical inquiries and further scrutiny during audits, reviews, or submissions.



Identify red and yellow flags before the official submission. Retrospective "correction" of raw data or planning errors is usually not permitted under regulatory guidelines.

## MiG - Services

We are a specialized preclinical CRO for medical device companies with a focus on in vivo studies, covering the entire preclinical development process.

- Preclinical study planning and evidence strategy: from Phase 0 scoping to GLP-compliant submission
- In vivo studies using large and small animal models, integrated histopathology, and complete QA documentation
- Regulatory interoperability as a design principle: GSPR mapping, MDR Annex II, FDA 21 CFR Part 58

**Contact us – in 30 minutes, we'll clarify what your project needs for the next phase.**

