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Artificial Intelligence in Toxicologic Pathology: A Review of Current Applications, Challenges, and Future Directions

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Abstract

Artificial intelligence (AI) has emerged as a transformative force in pathology, enabled by digital slide imaging and machine learning. In toxicologic pathology, AI has the potential to enhance efficiency, objectivity, and quantitative rigor in preclinical safety assessment. However, some significant challenges need to be addressed such as variability in data, model versatility, model validation, and regulatory acceptance. This review summarizes current AI applications in toxicologic pathology, outlines core benefits and limitations, and discusses the evolving role of the pathologist in an AI-augmented workflow.

1. Introduction

Toxicologic pathology integrates morphological assessment of tissues with clinical and exposure data to define test item-related effects in nonclinical studies. As whole slide imaging (WSI) is being adopted rapidly worldwide, histopathological slides have become amenable to computational analysis. Artificial Intelligence (AI) and machine learning (ML) methods, particularly deep learning, are now being applied to histological image interpretation in both clinical and toxicologic contexts, promising improvements in reproducibility and throughput while maintaining scientific validity (McGenity *et al.,* 2024; Turner *et al.,* 2020).

2. Digital Pathology: The Basis for AI Integration

Digital pathology converts glass slides into high-resolution images that can be processed by computational algorithms. Rapid adoption of digital pathology workflows is a prerequisite for AI implementation because it enables standardized image formats, scalable data storage, and remote review. However, toxicologic pathology poses unique challenges like multi-species differences, study-specific endpoints, and variable slide preparation practices that demand rigorous annotation and quality control for effective AI model training (McGenity *et al.,* 2024).

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3. AI Applications in Toxicologic Pathology

3.1 Tissue and Cellular Feature Quantification

Deep learning models can automatically segment tissue compartments and identify and quantify cellular features such as nuclei and cytoplasm. These models have been developed for quantitative evaluation of test item-induced morphologic changes, such as hepatocellular hypertrophy in rodents, demonstrating correlation with pathologist grading and ancillary endpoints (Pischon *et al.,* 2021).

3.2 AI-Assisted Lesion Detection and Grading

AI supports lesion detection and semi-quantitative scoring by highlighting regions of interest, measuring extent of lesion, and reducing observer variability. Such tools do not replace expert pathologists but can standardize assessments across large datasets and multi-site studies (Turner *et al.,*2021).

3.3 Biomarker Discovery and Pattern Recognition

AI models are capable of detecting histomorphologic patterns that correlate with molecular or clinical endpoints. Although these applications are more developed in clinical oncology, similar approaches are being explored in toxicologic contexts to link morphologic change with toxicodynamics. Systematic reviews in digital pathology broadly highlight the ability of AI to predict outcomes from histological images and extract complex image features (Zhang *et al.,* 2025; McGenityw *et al.,* 2024).

3.4 Cross-Study and Portfolio Analytics

Aggregating histopathology data from multiple toxicology studies enables trend analyses across compound classes, potentially improving safety signal detection and historical control use. These portfolio-level analyses are facilitated by AI-driven image search and normalization tools that index patterns across large slide collections (Parwani *et al.,* 2019).

4. Benefits of AI for Toxicologic Pathology

AI provides several advantages when properly validated:

- **Improved consistency and reproducibility:** AI models apply consistent criteria across slides and studies.
- **Increased throughput:** automated quantification can reduce time spent on repetitive tasks.
- **Quantitative objectivity:** reduces reliance on subjective scoring.
- **Better use of archival data:** enables retrospective mining of historical slides.

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These benefits depend on robust model training, validation, and pathologist oversight to ensure biologically meaningful outputs.

5. Challenges and Limitations

5.1 Technical Barriers

AI performance is sensitive to variations in staining, tissue preparation, and scanner platforms. Limited standardization in annotation of datasets across species and organs makes the generalization of the AI model difficult.

5.2 Explainability and Interpretive Challenges

Deep learning models often function as "black boxes," challenging interpretability. Explainable AI remains an active research area to bridge computational outputs with recognizable morphologic reasoning.

5.3 Regulatory and Operational Hurdles

Regulatory acceptance in toxicology relies on validated, traceable AI outputs with clear pathologist oversight. Operational integration requires data infrastructure and rigorous quality management systems.

6. The Evolving Role of the Pathologist

Rather than diminishing the role of toxicologic pathologists, AI amplifies it. Pathologists define biologically meaningful endpoints, curate training data, interpret AI outputs in context, and remain ultimately responsible for safety decisions. Collaboration with data scientists and informaticians will be increasingly important.

7. Future Directions

Future innovation is likely to include:

- **Multimodal AI** integrating histology, clinical pathology, and molecular data across different species.
- **Collaberative learning** enabling cross-institutional model training without data sharing.
- **Standardization initiatives** for digital pathology and AI validation.

These developments aim to make AI a more robust and generalizable tool in safety assessment while maintaining scientific integrity.

8. Conclusion

AI in toxicologic pathology offers compelling opportunities to increase efficiency and objectivity. Successful implementation requires high-quality digital images, rigorous

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validation, and continued pathologist leadership. AI is best viewed as an enabling technology that enhances toxicologic pathology workflows without replacing expert judgment.

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