ENDPOINT
PRECLINICAL

30+ Experts!

Expertise in Pathology & Toxicology

Who We Are

Endpoint Preclinical provides access to board-certified pathology and toxicology expertise for nonclinical safety programs through a coordinated consulting network. Capabilities include microscopic interpretation, quantitative and digital pathology workflows, toxicologic risk assessment, independent peer review, and regulatory-facing reporting aligned with study objectives.

Our network also supports production-level small animal surgical services for toxicology and dosing studies, including on-site vascular and non-vascular cannulations. These programs are structured to support catheter patency, animal welfare standards, and consistent sampling within TK, PK, and PD study designs—all through a single contracting partner.

We make complex science practical by connecting the experts who define, interpret, and defend it.

Why Endpoint

- **Integrated Expertise:** Board-certified experts aligning study design, data generation, and regulatory expectations from the outset.
- **From Microscopy to Risk Assessment:** Correlation of morphologic, clinical, functional, and material endpoints to define biological relevance and human health risk.
- **Therapeutic & Device Alignment:** Expertise spanning small molecules, biomolecules, cell and gene therapies, medical devices, and combination products—including biocompatibility and E/L strategy.
- **Peer Review & Data Integrity:** Independent pathology peer review and defensible interpretation aligned with international best practices.
- **Scalable Collaboration:** Engage a single expert or deploy a coordinated team to match your program's needs.

Pathology & Toxicology Capabilities

Area	Representative Expertise
Anatomic & Toxicologic Pathology	Microscopic evaluation of tissues across nonclinical species; lesion characterization; semi-quantitative grading; phenotyping of disease models; efficacy and safety assessment; GLP-aligned study support; pathology peer review.
Clinical & Correlative Pathology	Integration of hematology, clinical chemistry, and morphologic findings with functional and systemic endpoints to determine biological and toxicologic significance.
Digital & Quantitative Pathology	Histomorphometry; immunohistochemistry and in situ hybridization interpretation; multiplex assays; whole-slide imaging; AI-enabled image analysis; quantitative biomarker assessment.
Toxicology Strategy & Risk Assessment	Design of preclinical safety strategies; hazard identification and characterization; toxicologic risk assessment; integration of pharmacokinetic and mechanistic data; human health hazard evaluation.
Biocompatibility & Materials Evaluation	Extractables and leachables strategy; materials of concern assessment; particulate and residual evaluation; alignment with ISO and global regulatory standards.
Regulatory Submission Support	Preparation and review of nonclinical safety sections; alignment with IND, IDE, PMA, 510(k), and global submissions; regulatory interaction support and data defensibility.
Study Design & Program Oversight	Endpoint selection; tissue collection strategy; model selection; CRO evaluation and placement; study monitoring; integrated evidence generation planning.
Production-Level Surgery	Vascular and non-vascular cannulation services supporting PK, PD and TK studies; catheter placement and maintenance to preserve patency and serial sampling; alignment with study endpoints, welfare standards, and downstream evaluation.

**Our network supports studies across all preclinical species and therapeutic modalities, from exploratory through GLP-compliant pivotal programs.*

How to Get Started

1. Discovery Meeting

Meet with our leadership team to discuss your research goals, challenges, and timelines. We'll identify the right experts within our network to support your program needs.

2. Sign an MSA

One master agreement allows your organization to access multiple consultants, capabilities, and service types, without renegotiating terms for each consulting engagement.

3. Access Expertise

With your MSA in place, our experts can integrate into your research programs immediately. Our network scales your team—from study design to regulatory support—as your needs evolve.

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