



Rethinking Toxicology:

Smarter Paths Beyond Animal Testing

The Future of Toxicology Is Changing

- + FDA is actively supporting New Approach Methodologies (NAMs)
- + Movement toward reducing animal testing requirements
- + Increased emphasis on human-relevant data models

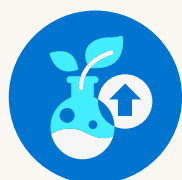
What's Driving the Change

PILLARS:



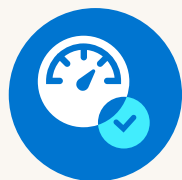
Regulatory Momentum

- FDA guidance + announcements encouraging alternatives



Scientific Advancement

- Organoids, in vitro systems, computational models



Speed & Cost Pressure

- Faster IND-enabling timelines



Ethical Expectations

- Reduction in animal use

But Here's Where Problems Break Down



"What alternatives are actually acceptable to the FDA?"

"How do we validate non-animal data?"

"When should we engage the FDA?"

"How do we integrate NAMs into existing programs?"

"What belongs in a briefing package?"

What the FDA Actually Expects



Justify Your Approach

- Scientific rationale for NAMs
- Relevance to human biology



Demonstrate Reliability

- Validation strategy
- Fit-for-purpose data



Engage Early

- INTERACT / Pre-IND
- Clear briefing materials

From Uncertainty to a Defensible Strategy – How Syner-G Can Help

- Evaluate your current toxicology program
- Identify where NAMs can be integrated
- Develop regulatory strategy + justification
- Write FDA-ready briefing packages
- Facilitate FDA interactions and meetings

As regulatory expectations evolve, toxicology programs must do more than reduce animal use. They must demonstrate scientific rigor, regulatory alignment, and a clear path to decision-making. With the right strategy, companies can reduce reliance on animal studies, strengthen regulatory confidence, and accelerate development timelines. If you are evaluating how to evolve your toxicology approach or integrate new methodologies into your program, Syner-G can help you navigate the path forward with an informed, data-driven approach.