

Is Your IND-Enabling Tox Program Strategically Ready?

A SELF-CHECK FOR IND-BOUND PROGRAMS

This checklist outlines common elements of IND-enabling toxicology programs. Completion does not equal strategic or regulatory readiness.

PROGRAM STRATEGY

- Clinical indication defined
- Route and duration aligned
- Species selection justified
- NOAEL, TK, margins aligned
- DC nomination criteria defined
- IND nomination criteria defined

CMC CONSIDERATIONS

- Batch strategy aligned to tox timing
- Impurities assessed
- Metabolite needs assessed
- TA quantity sufficient
- TA readiness aligned

SUPPORTING STUDIES

- PK supports dose decisions
- Secondary pharmacology scoped
- Safety pharmacology appropriate
- Immunotox relevance assessed
- Genotox strategy defined

NON-GLP STUDIES

- Single-dose study justified
- MTD design appropriate
- DRF endpoints sufficient
- Timing sequenced correctly
- CRO scope appropriate
- Bioanalysis aligned
- Reporting fit-for-purpose

GLP STUDIES

- TA characterized
- CRO strategy defined
- Target organ framework in place
- Endpoints decision-driven
- Dose levels scientifically justified
- Schedule is IND-aligned
- Reporting defensible

IND SUBMISSION

- NOAEL/HNSTD/STD10 established
- Human starting dose justified
- Defensible narrative in place

If this raised uncertainty, a Nonclinical Strategy Audit may be needed. [Learn more.](#)