Prepare for the pre-IND meeting

Your drug substance and clinical plan

What is your mechanism of action, and how well do you understand it?

How well characterized is your drug substance?

What is your plan for clinical trials?

Be prepared to discuss study design, clinical partners, subject recruitment, dosages, and check points.

CMC: chemical, manufacturing and control

These aspects of your manufacturing have regulatory implications.

- Where will the drug be manufactured? By whom?
- How is the facility maintained?
- What type of technology will be used?
- What consumables will be used?

Where are they produced?

Can you validate your materials? (e.g., for extractables and leachables)

- Your process, reproducibility and robustness
- What are your process controls?
- How will you guarantee your drug is not adulterated?
- What are the critical quality attributes (CQAs), and how will you test them?

Toxicology

Be prepared to describe your pre-clinical trials plan, implementation and results. What adverse effects were noted?

What dosages were used, and what levels of dosage caused unacceptable adverse effects?

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