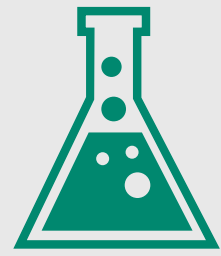


# Prepare for the pre-IND meeting



## 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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