

Manufacturer's Pre-Panel Checklist

- Review the purpose and scope of the advisory committee
- Identify the FDA's key discussion and voting questions
- Understand whether the focus is safety, effectiveness, or benefit-risk
- Prepare complete and well-organized briefing documents
- Ensure clinical data are accurate and clearly summarized
- Verify nonclinical and bench testing data are consistent
- Confirm statistical analyses are justified and reproducible
- Highlight key benefits and known device risks
- Clearly explain risk mitigation and control measures
- Prepare concise and focused presentation slides
- Align device description with intended use and labeling
- Review proposed claims for regulatory compliance
- Review prior panel transcripts and FDA briefing documents for similar devices to anticipate regulatory expectations
- For the briefing documents, if certain information is believed to be exempt under FOIA, prepare two versions—one unredacted and another publicly releasable version (redacted)
- Anticipate panel concerns and likely questions
- Prepare clear, evidence-based responses
- Conduct mock panel rehearsals internally
- Assign trained clinical and regulatory presenters
- Confirm roles and speaking timelines
- Verify FDA submission formats and deadlines
- Align internal teams on messaging and data interpretation
- Prepare for post-panel FDA follow-up requests