

# Preparing Your Team for FDA Inspection

---

One of the aspects of an FDA inspection that we frequently mention is that you should use a cross-functional team within your company to participate and help prepare for it. It helps to have knowledge and expertise across different areas of the business.

It is important to know what to look for ahead of an FDA inspection. Here are a few things to review and have ready for the inspector:

- Prepare a control room. This serves as the base from which the inspector can set up for the inspection.
- Have a procedure in place for the inspection. Who will be a “runner?” Who needs to provide what? Are people trained, including your receptionist?
- Conduct a mock inspection, including interview techniques.
- Review the documentation that the inspector may ask for / is allowed to review and understand which documents they should not review (for example, internal audits or management reviews).
- Review complaints, any medical device reports, service reports and recalls going back at least three years. Link this review to CAPAs taken and final resolution, if any. Review the corrective action log.
- Review your risk management file, design history file, device master record and device history records for accuracy. Ensure that there are linkages between the latter three.

For more resources, check out:

[How to Prepare Your Design History File for FDA Inspection](#)  
[Tips to Help Your Prepare for an FDA Inspection](#)