REDICA Systems

Checklist: Interacting With FDA During Review Process

REPORT

PUBLISHED BY

REDICA SYSTEMS
6800 KOLL CENTER PARKWAY
SUITE 120
PLEASANTON, CA 94566

SALES@REDICA.COM
844-332-3320

CHECKLIST:
INTERACTING WITH FDA DURING THE DRUG REVIEW PROCESS

☐	DON'T: Contact your drug reviewer directly. **DO: Work through a project manager.**
☐	DON'T: Ignore your device reviewer if called directly. **DO: Answer! Ask them how you can be prepared for their call.**
☐	DON'T: Complain about the cost of meeting a regulatory requirement. **DO: Ask for explanation or clarification on the requirements.**
☐	DON'T: Get caught in a lie. **DO: Think of FDA as your partner—be truthful, forthright, up front and transparent.**
☐	DON'T: Fail to check available guidance. **DO: Utilize FDA's website—most of the guidance has been written or updated in the last 5-10 years.**
☐	DON'T: Submit changes requiring prior approval in an annual report. **DO: Check guidances to determine how changes should be filed, or contact the project manager if the guidance is unclear.**
☐	DON'T: Submit minor changes in the annual report. **DO: Use a risk-based approach—"Does this change have any impact on our GMPs?"**
☐	DON'T: Raise questions in a meeting with FDA that were not in the briefing document. **DO: Brainstorm questions ahead of time and narrow down to roughly half a dozen.**
☐	DON'T: Fail to be adequately prepared for an FDA meeting. **DO: Practice with your team. Have one person play as the FDA and raise issues, object to positions.**
☐	DON'T: Tell FDA that your approach was OK for an EU submission. **DO: Ask for supporting regulation, guidance, or scientific rationale.**
☐	DON'T: Blow off regulators' advice. **DO: LISTEN. For example, if you have clear advice of how to go from Phase II to Phase III, your asset is worth a lot more. Advice from FDA is of enormous interest to potential investors or purchasers.**