Sample Mock FDA Audit & Gap Analysis Agenda

*Assumes consultant has already reviewed firm's SOP index, critical SOPs and any auditor prep package.

DAY ONE

9:00–9:15 a.m.: Consultant arrival and presentation of mock inspection letter to reception. The letter specifically states the firm should follow its SOP for the arrival of an FDA or any other regulatory health agency inspector.

9:15–10:00 a.m.: Opening meeting with firm and discussion of audit logistics, including:

- Reaffirm the audit plan
- Review the four levels of criteria used in the assessment
- Explain the record collection and sampling techniques
- Explain the reporting process and categorization of findings

10:00–10:30 a.m.: Facility tour

10:30 a.m.–Noon: Overview of compliance environment to include organizational charts, roles and responsibilities of QA, RA, records management, IT and other departments responsible for supporting and enforcing the quality system, critical supplier (CRO, CMO, contract sterilizer, etc.) lists, site master file (if any), and scheduling of afternoon interviews.

Noon–1:00 p.m.: Lunch

1:00–4:30 p.m.: Review of internal quality files such as written procedures, internal audits, training/qualification of QA personnel, and sample training documentation (such as from critical SOPs). Interview core QA personnel (and RA personnel as time permits).

4:30–5:00 p.m.: Recap meeting with firm of Day One audit progress, findings and questions; make requests for interviews for the next day.

DAY TWO

9:00 a.m.–Noon: Review of records retention policy and schedules, management controls, and policies associated with e-data integrity and long-term data archival/retrieval. Test controls, policy and SOP proof, quality system management review reports, etc. Interview personnel identified at the end of Day One.

Noon–1:00 p.m.: Lunch

1:00–4:30 p.m.: Review product controls at the site (specific to product/site) such as:

- Production run preparation/cleanup
- Labeling, product inventory and segregation
- Raw materials (receiving, quarantine, storage, etc.)
- Shipping and receiving (distribution)
- Product returns, reworks, reprocessing, etc.
- Annual product reviews

4:30–5:00 p.m.: Recap meeting with firm of Day Two audit progress, findings and questions; make requests for interviews for the next day.

DAY THREE

9:00 a.m.–Noon: This day will focus on CAPA, complaint handling, and supplier oversight. Interview personnel identified at the end of Day Two.

Noon–1:00 p.m.: Lunch

1:00–4:30 p.m.: Review supplier controls at the site (specific to product/site) such as:

- Supplier evaluation and qualifications
- Supplier contractual controls/quality agreements
- Supplier monitoring and oversight
- AVL management
- Dealing with supplier problems, improvement plans, etc.

4:30–5:00 p.m.: Recap meeting with firm of Day Three audit progress, findings and questions; make requests for interviews for the next day.

DAY FOUR

9:00 a.m.–Noon: Review remaining compliance program sections including quality by design, design control, etc. Interview any personnel identified at the end of Day Three.

Noon–1:00 p.m.: Lunch

1:00–2:30 p.m.: Interview any remaining personnel and/or conduct follow-up clarifications from earlier audit questions.

2:30–4:00 p.m.: Consultant time to wrap-up and prepare for exit meeting.

4:00–5:00 p.m.: Exit meeting with firm; review of critical vs. minor findings, suggested actions/opportunities for prioritized remediation, answer questions, discussion of next steps (report drafting, etc.).