
GENERAL PROCEDURES POLICIES

Process on GAO/OIG Studies/Audits:

- CVM liaison receives notice from FDA Office of Planning (OPL) of start of new study/audit and determines if subject impacts CVM. If there is any question about whether a particular study will involve CVM, the CVM liaison will clear it with the Senior Management Team.
- CVM liaison will inform SMT (via e-mail) of start of new GAO/IG study/audit and suggestion of who CVM participants/entrance conference attendees should be. If the GAO/IG study/audit has major relevance for CVM, provide SMT any relevant information.
- CVM liaison will provide FDA OPL names of CVM participants to attend entrance conference.
- CVM liaison will provide CVM participant(s) with any relevant material transmitted regarding this audit/study, including FDA ground-rules in interacting with GAO.
- GAO will provide FDA with questions to be addressed at the entrance conference.
- CVM liaison will prepare any needed material prior to internal pre-meeting.
- CVM liaison and CVM participant(s) will attend pre-meeting.
- CVM liaison will prepare any needed material prior to GAO/IG entrance conference.
- CVM liaison and CVM participant(s) will attend GAO/IG entrance conference.
- Throughout the duration of the study/audit, CVM liaison will interact with OPL in providing GAO with requested information.
- During the course of an audit/study, the CVM liaison will inform SMT of any relevant information that arises that may be controversial, etc.

- Near the end of a study, GAO will provide FDA with a “Statement of Facts” which is prior to GAO providing FDA with their draft report. The Statement of Facts contains information GAO collected during the study. It does not contain their recommendations. The CVM liaison will review GAO “Statement of Facts” and provide it to CVM participant(s) involved in study and also inform CVM participant(s) of any concerns with it. If the “Statement of Facts” have a significant impact on CVM, CVM liaison will brief the SMT on the issue prior to responding to it. In preparing response to “Statement of Facts”, CVM liaison will draft or coordinate responses, with appropriate input from CVM participant(s), and send to SMT for clearance as needed if controversial.
- On most occasions, FDA will hold an FDA internal meeting to discuss the Agency’s comments to the Statement of Facts.
- CVM liaison, along with CVM participant(s) will attend exit conference. If any relevant information arises at exit conference, liaison will inform the SMT via e-mail or briefing.
- CVM liaison will review GAO/IG draft report and provide a brief summary of draft report to program folks involved in study. If the findings of the report will have a significant impact on CVM. Liaison will brief the SMT on the issue prior to responding to recommendations. In preparing responses to GAO/IG recommendations, CVM liaison will draft or coordinate responses, with appropriate input from CVM participant(s) and send to SMT, as needed, if controversial for clearance.
- The CVM liaison will keep GAO/IG status table updated. This table will be located on the “O” drive at O:\old_root\GAO

NOTE:

- Wherever CVM liaison is referenced in this document, it refers to CVM GAO or CVM IG liaison.
- All GAO/IG audits/studies will be entered into the CVM tracking system.
- Any information shared with GAO needs to go through the CVM and FDA GAO liaison (OPL).
- Prior to any meeting between CVM and GAO, the CVM liaison will ask for advance questions.