

Company Name	Procedure Number:	Page 9 of 17
Title: Hosting Regulatory Inspections	Implementation Date:	Version Number 1.0

- If the Inspector/Investigator requests a copy of a source document to take with them, the EMC will make two photocopies, one for the Inspector/Investigator and one for the Inspection File.
- Enter the document into the Evidential Material List and note that a copy was taken.
- Stamp the Inspector/Investigator's copy, "Copy-Proprietary and Confidential" and forward it to the Runner.

5.4.2 Daily Debriefing Meetings

- If the inspection lasts for more than a day the Inspection Coordinator will facilitate a debriefing meeting at the end of each day of the inspection.
- The debriefing meeting will be convened in the conference room with the Inspector/Investigator, Inspection Coordinator, Head of Regulatory, Scribe, Runner, area management and any Subject Matter Experts that were questioned that day, as decided by the coordinator.
- Short summary of the inspectors/investigators impressions of that day's inspection.
- A plan for the next days inspection, including what documents can be prepared for review will be discussed.

5.4.3 Daily Internal Meetings

- If the inspection lasts for more than a day the Inspection Coordinator will facilitate an internal daily summary at the end of each day of the inspection.
- The coordinator inform the team about the day and the Scribes complement this information with their notes
- During this internal summary assignment of tasks, including responsibility and target completion dates, will be assigned. Organization of starting corrective actions (if realistic) will be conducted.
- Scribes finish their daily reports and inform all involved people, experts and upper management (e-mail) about the day, the program for the next day, availability of experts, necessity for documents etc.

5.4.4 Inspection Closing Meeting

- At the completion of the inspection the Inspection Coordinator will convene a closing meeting in the conference room with the Inspector/Investigator, Inspection Coordinator, Head of Regulatory, Scribe, Runner, area management, site manager and any Subject Matter Experts as required.
- The Scribe will initiate an, "Opening and Closing Meeting Attendance-Regulatory Inspections" form and pass it to the meeting attendees for signature. In case of FDA Investigator may also sign.