1. OBJECTIVE

The purpose of this Standard Operating Procedure is to describe the process for preparation, conduct, and follow-up of regulatory authority inspections associated with [Company] studies or products.

1. **SCOPE**

Sections 6.1 – 6.1 below apply to any regulatory authority inspection conducted at a [Company] facility. Section 6.5 applies to any regulatory authority inspection associated with any [Company] product, program, or study conducted at a third-party facility (e.g., investigative site or vendor facility).

1. Definitions

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| Term | Definition |
| Inspection Readiness and Management System (IRMS) | Platform used to generate and fulfill inspection requests and hold other information, such as storyboards, used by inspection teams to prepare for and conduct inspections. |
| Inspection Team | Personnel who facilitate an inspection and fulfill inspection requests, including the Host, Communicator, Assigner, Subject-Matter Experts, Reviewers, Scribe, and other support staff. |
| Inspector | Regulatory authority lead who conducts a regulatory inspection. In the US, personnel who conduct inspections are sometimes called “investigators.” |

1. Responsibilities

Responsible roles for tasks are described in the Procedure section, below. Tasks may be delegated to a qualified resource, but the role named remains accountable for completion.

1. REFERENCES
	1. SOP-[X Company Deviation and CAPA SOPs]
2. PROCEDURE
	1. [Company] Inspections: Inspection Preparation

| Role | Step |
| --- | --- |
| Quality Assurance Lead | 1. Under conditions in which the risk of an inspection is elevated,
	1. Oversee development of an inspection plan, including identification of inspection team roles, responsibilities, and personnel; set-up of Inspection Readiness and Management System (IRMS); set-up of inspection rooms; processes for document retrieval; and timeline for preparatory activities, including quality control reviews, audits, review of prior internal audit reports and regulatory authority inspection reports, interview practice, and (if appropriate and time permitting) mock inspection.
	2. Work with functions to be inspected and vendors who will support inspection to facilitate preparatory activities per inspection plan.
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| Quality Assurance Lead | 1. Upon notification of an announced inspection, communicate with inspector to ascertain inspection scope, inspector’s preferred method of document sharing, and pre-inspection requests, if any.
2. Work with inspection team to generate and fulfill any pre-inspection requests in the Inspection Readiness and Management System (IRMS).
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* 1. [Company] Inspections: Receiving Inspector at [Company]

| Role | Step |
| --- | --- |
| Reception | 1. Upon arrival of regulatory authority inspector, perform the following tasks:
	1. Ensure the inspector has signed the site register.
	2. Notify the Host of the inspector’s arrival.
		1. For unannounced inspection, notify the Head of Quality Assurance and then the personnel on the call list in the order described in the inspection plan or, alternatively, notify the Head of Quality Assurance and then the members of the Executive Team. The most senior person available determines who will fulfill the role of Host.
	3. Retain inspector in the reception area until the Host or designee arrives to escort them.
	4. Notify all staff of the inspector’s arrival.
	5. Do not review or sign any documentation presented by the inspector.
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| Host | 1. Greet the inspector and review their credentials.
2. Escort the inspector to a secure conference room.
3. Confirm the scope of the inspection. For FDA inspections, obtain a copy of the FDA Form 482 (Notice of Inspection).
4. If the inspection was not previously announced,
	1. Assemble the appropriate Inspection Team to best address the inspection scope.
	2. Instruct the inspection team to obtain and review relevant related internal audit reports and previous regulatory authority inspection reports to identify potential issues that may be addressed.
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* 1. [Company] Inspections: Hosting the Inspection

| Role | Step |
| --- | --- |
| Host | 1. Facilitate the inspection as follows:
	1. Designate a Communicator to capture inspection requests.
	2. Designate an Assigner to assign requests to appropriate Subject Matter Experts.
	3. Designate Subject Matter Experts to respond to requests related to various functional areas.
	4. Designate Reviewers to review each response for adherence to Good Documentation Practice and relevance to the request.
	5. Designate a Scribe to take notes on discussion topics.
	6. Ensure that the inspector is escorted by a [Company] representative within the [Company] offices.
	7. Facilitate a site tour, if requested.
	8. Facilitate interviews with appropriate Subject Matter Experts.
	9. Facilitate inspector access to electronic systems, if requested and if access can be restricted to the inspection scope; if access cannot be restricted to inspection scope, work with inspector and Legal on an alternative to fulfill inspection requests.
	10. If the inspector requests company financial records or personnel files (other than qualifications or job descriptions), or if the inspector asks any employee or contractor to review or sign an affidavit, obtain Legal counsel before taking further action.
	11. Request a debrief from the inspector at the end of each day.
	12. Provide a daily summary to senior management and other relevant functional heads.
	13. Facilitate the closing meeting with the inspector and receive any inspection output and/or observations.
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| Inspection Team | 1. Maintain all inspection-related requests, responses, and communications within the IRMS unless otherwise directed by the inspection plan.
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* 1. [Company] Inspections: Inspection Follow-Up

| Role | Step |
| --- | --- |
| Host | 1. Conduct a final debrief meeting with the inspection team to review inspection output, observations, and feedback on the inspection process.
2. Work with Functional Heads to facilitate a written response to observations and/or final inspection report.
3. As needed, generate deviations and CAPAs per SOP-[X].
4. Lock the inspection in the IRMS, download the following archives from the IRMS, and file them in the Quality Assurance repository:
	1. Record of inspection requests
	2. Record of inspection responses
	3. Copy of all documents provided to the inspector
	4. Identification of all documents retained by the inspector
	5. Scribe notes
	6. Communications
5. File the following in the Quality Assurance repository:
	1. Correspondence with the inspector/regulatory authority concerning the inspection
	2. Observations
	3. Inspection Report
	4. Observation/report responses
6. Confirm that vendors are notified of any product or service-related observations as required by Quality/Technical Agreements
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* 1. Third Party Inspections

| Role | Step |
| --- | --- |
| [Company] Representative | 1. Upon notification of an announced or unannounced regulatory authority inspection of an investigational site or GCP vendor in conjunction with any [Company] product, program, or clinical study, notify the Head of Quality Assurance.
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| Head of Quality Assurance | 1. Assign a Quality Assurance Lead or Functional Lead to support the third-party inspection.
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| Quality Assurance Lead or Functional Lead | 1. Oversee development of an inspection support plan, including identification of inspection support team roles, responsibilities, and personnel; inspection support processes; and timeline for preparatory activities.
2. Set up an inspection in the IRMS to handle any requests that the third party sends to [Company] representatives during the inspection.
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| Inspection Support Team | 1. Support the third-party inspection according to the inspection support plan.
2. Capture and fulfill requests sent to the Inspection Support Team as described in section 6.3 above, retaining all relevant documentation in the IRMS.
3. At the close of the inspection, request a copy of the inspection output and/or observations and confirm timeframes and process for response.
4. Work with the third party to support development of the inspection response, as appropriate.
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| Quality Lead | 1. Conduct a final debrief meeting with the inspection team to review inspection output, observations, and feedback on the inspection support process.
2. As needed, generate deviations and CAPAs per SOP-[X].
3. Lock the inspection in the IRMS, download the following archives from the IRMS, and file them in the Quality Assurance repository:
	1. Record of inspection requests to [Company], if any
	2. Record of inspection responses from [Company], if any
	3. Copy of all documents provided in inspection responses by [Company]
	4. Communications
4. File the following in the Quality Assurance repository, if provided by third party:
	1. Correspondence with the inspector/regulatory authority concerning the inspection
	2. Observations
	3. Inspection Report
	4. Observation/report responses
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1. DOCUMENT HISTORY

| Version | Document History/Description of Revision | Author | Date |
| --- | --- | --- | --- |
| 1.0 | Original version | [Name] | Current |

1. Approval

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| [Name, Title] |  | Date |
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| [Name, Title] |  | Date |