Get Ready for Inspections



How to use Ready Room to prepare for, manage and follow up a GXP inspection.



THROUGHOUT THE REGISTRATION STUDY

- Develop storyboards to describe quality issues and plan responses to inspection questions
- Import storyboards from over 160 GMP and GCP templates, or create your own
- Attach or link documents and use rich text and images to create the quality story



PRIOR TO MOCK INSPECTION

- Create a Ready Room training inspection
- Identify internal and external subject-matter experts and assign them to the inspection
- Train team on logistics of fulfilling requests
- Practice responding to interview questions

- Unlimited training, mock, and live inspections included
- Unlimited users, so you don't have to count seats
- Use restricted view for external personnel so they can only see documents they upload
- Assemble personalized storyboard decks and use flashcards to practice answering questions



MOCK INSPECTION

- Create a Ready Room mock inspection
- Copy storyboards
- Conduct mock inspection

 Ready Room's inspection board connects remote and on-site team members and mock inspectors, so teams can participate remotely, saving time and money



AFTER FORMAL NOTIFICATION OF THE INSPECTION

- Create live inspection
- Invite inspection team members and assign personas
- Determine preferred delivery method for documents
- Set up in a few minutes
- Inspectors can review documents through Ready Room, via Box integration, or other methods
- Box integration configures in seconds and permits document uploads without leaving Ready Room



UP UNTIL THE INSPECTION

- Create preliminary requests and drive responses and documents through the workflow
- Stage anticipated requests, responses, and documents and drive through workflow
- Release pre-inspection documents early or hold until inspection start
- Ready Room manages staged requests via a separate workflow, so they won't be accidentally released before requested



UP UNTIL THE INSPECTION (continued)

- Schedule video briefings for team meetings, virtual backroom, and interviews
- Integrated briefings connect all Ready Room team members through a single platform without leaving the inspection
- People outside the inspection can be invited, too



THROUGHOUT INSPECTION

- Capture inspector requests
- Assign requests to SMEs
- Answer inspector questions or upload documents
- Review responses
- Release requests to Inspector
- Capture scribe notes
- Strategize and collaborate over voice, video, and chat
- Monitor request status

- All team member displays are kept synchronized in real-time
- Requests can be filtered by inspector so a "sub-team" per inspector can focus on relevant requests
- Ready Room sends notifications and allows assignees to filter the board to focus on their requests
- A request can handle an unlimited number of documents, in any format
- Staged requests and storyboards can be activated for release
- Team members can add comments and promote or demote requests
- An audit trail allows reviewers to see who has interacted with each request
- Release via Ready Room, copy cover sheet and documents to Box folder, or download for manual delivery
- Ready Room permits an unlimited number of scribe feeds to capture discussion points
- Team members can monitor one or more feeds in separate tabs
- The color-coded inspection board communicates the status of each request at a glance



POST REPORT

 Refer to Ready Room while responding to findings to confirm which documents the inspector saw and to review debrief notes



LESSONS LEARNED

• Use Ready Room to evaluate areas of focus and delivery metrics, identifying opportunities for improvement

READY TO GET STARTED?

Visit <u>readyroom.net</u> or email <u>info@readyroom.net</u> to schedule a demo. Get ready.

