READY ROOM

Blueprint Medicines is Ready

Opportunity

Blueprint Medicines, a biotechnology company located in Cambridge, MA, completed a round of regulatory inspections for its first marketed product using a combination of tools to capture, log, and track request fulfillment, upload documents, and release responses. This set-up required making frequent manual hand-offs. Some examples:

- Inspection requests were captured in electronic scribe notes in the inspection room and then transcribed into an Excel tracker in the back room.

- Inspection team members needed to reach out to assignees via email, phone, or text to alert them to new assignments.

- Documents were moved from one Sharepoint folder to another to facilitate QC and review, with status changes transcribed on the tracker with each move.

- Two runners carried messages between front and back rooms to clarify and reconcile requests.

The inspections were successful, but the team sought a better solution for subsequent inspections. When a global pandemic triggered working from home, and regulatory authorities started to announce remote inspections, Blueprint Medicines recognized an opportunity to implement a solution that could support both in-house and remote inspections.

Company

Blueprint Medicines Corporation is a biotechnology company developing therapies for patients with a broad range of genomically defined cancers and rare diseases.

Issue

Inspection management tools required making frequent handoffs, a process that would not translate well to a remote inspection scenario.

Solution

Ready Room provided the speed, transparency, and connectedness for the team to manage two successful mock inspections, including one "compressed" mock BIMO inspection where they delivered over 700 documents in a single day.

*"With a tailored **technology solution**, we were able to **optimize cross-functional collaboration** to ensure rapid and accurate responses to inquiries from regulatory authorities."*

A Quick Start

The team planned two mock inspections with Ready Room, one GCP and one GMP. After the Blueprint Medicines account was configured — a five-minute process —the Quality Assurance team of inspection facilitators attended a one-hour training to review system functionality and practice setting up inspections, creating inspectors, managing users, and inspection team operations. A second one-hour training was held with each inspection team to run through the process of fulfilling requests, filtering the inspection board, and reviewing the audit trails.

At these sessions, the teams were introduced to the concept of personas — roles with color-coded avatars that correspond to the area of the inspection board that each persona is intended to manage. The purple Communicator avatar, for example, helps keep the people assigned to the Communicator persona focused on the task of assigning new requests (the purple button). The red Assigners were dedicated to assigning requests in the red column and moving them to the orange Fulfill column. Yellow Ready Room Reviewers checked requests that appeared in the yellow column; green Inspection Hosts released requests from the green column. Personas can be changed by users at any time to facilitate quick shifts in responsibilities during what is typically a long inspection process.

Inspecting from Home

For the GCP mock inspection, all team members and mock inspectors worked remotely. To reduce strain on a team that had other deadlines to meet, the inspection was compressed: two mock inspectors ran through most of the BIMO agenda in a single day. A team of 15—two Communicators, two Hosts, two Ready Room Reviewers, and multiple SMEs--worked in two streams, capturing over 80 requests and transferring over 700 documents totaling more than one gigabyte of data.

*"We did a lot in one day. A LOT. It was **super-easy to upload** documents."*

Ready Room's ability to differentiate between multiple inspectors helped the two Communicators keep pace with the rapid requests. Assignees who were working on other activities throughout the day appreciated the email notifications: "Emails came through immediately. Getting to see a brief description of the request in the email was nice. Clicking on the link took you right to the request." When one team member had to "step out" of the inspection to attend to other tasks, it was an easy matter to reassign the task. The inspection board was surprisingly "tangible" for a team accustomed to working in the same physical space. One team member noted, "I found the process pretty transparent. It gives you an exact idea as to who is working on what." Small user interface touches, like the "aura" that persists after a user interacts with a request, or the filtering system that lets users see only tasks that are assigned to them, were helpful to the team managing 80 different requests.

Cross-Continental Inspection Team

The GMP mock inspection featured a smaller team with an on-site host and mock inspector in Europe; subject-matter experts from both Blueprint Medicines and a vendor participating remotely; and a QA team supporting the inspection from home starting in the early hours in the US.

With a more limited scope, the QA team had a good idea of which documents the mock inspector would request, so they staged approximately 50 documents in Ready Room prior to the inspection start, generating requests, assigning Subject Matter Experts, attaching documents, QCing them, and moving them to the point of release.

During the inspection, the GMP team used the Chat feature to keep front and back rooms connected. The "no-refresh" updating enabled by Ready Room's use of Phoenix LiveView technology was a great benefit: the EU team could see a US team member moving requests through the workflow or reprioritizing requests in the columns as it was occurring.
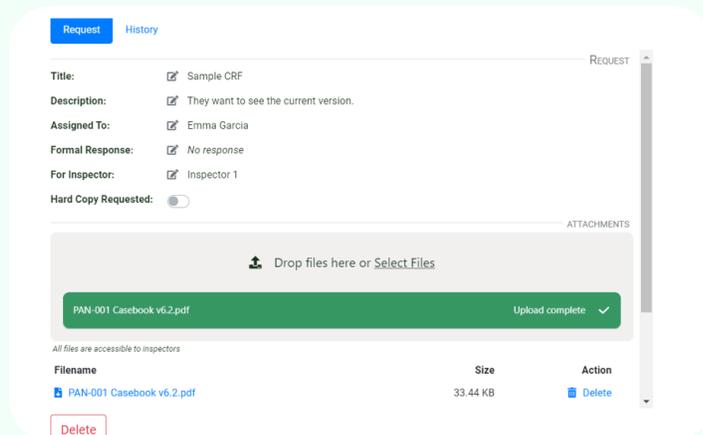
*"It was helpful to see the **history of people interacting with the request,** to be able to tell when it changed hands."*

Speed, Transparency, and Connectedness

Ready Room decreased the redundancy and number of handoffs inherent in Blueprint Medicines' previous logistics set-up:

Ad Hoc Logistics Solutions	Ready Room
▬ Inspection team transcribes requests from scribe notes to spreadsheet	✓ Request is captured in the system with a few keystrokes, with editable metadata
▬ Inspection team must copy/paste or move documents from folder to folder to simulate status changes and facilitate review	✓ Documents attached to requests in Ready Room "travel with" each request automatically
▬ Inspection team members must notify remote assignees of tasks	✓ Ready Room automatically notifies assignees
▬ Runners and instant messaging are used to clarify requests	✓ Integrated comments provide a permanent history of clarifications
▬ Inspection team members update request log with status changes	✓ Ready Room automatically tracks status changes

"I Can Relax"

Inspections are fraught activities at the best of times, and the prospect of a remote inspection while working at home would be daunting for any team. "I'm so glad we did the Ready Room pilot," one of the QA facilitators said. "We would never have been able to handle that volume in that short of time. Now we know we can handle a remote inspection. I can relax."

Ready to Get Started?

Visit www.readyroom.net, email info@synclinical.com, or call us at (978) 880-3242 to schedule a demo.

Get ready.

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