



SAFETY ASSESSMENT

Remote Audits

A secure, flexible solution for QA audit activities

 [Contact us to get started](#)

Introduction

The disruption wrought by the COVID-19 pandemic reminds us in CRO industry that the programs that survive a crisis are those that evolve. Taking an agile, flexible approach to operations allows us to adapt to change, minimize damage and delays, and sustain progress. While regulated research is governed by standards, there is room for innovation and creative solutions that overcome challenges.

Traditionally completed in person, tasks like due diligence and qualification audits allow Sponsors to oversee their contracted or outsourced work. In the case of global travel bans, shelter-in-place directives, and social distancing, these critical site visits are suddenly not feasible. With an eye toward such possibilities, Charles River has proactively invested in the technology resources and business continuity plans to effectively address the need for remote collaboration.

While borne of necessity, moving to a virtual model for the conduct of QA audit activities offers distinct advantages. Not only does it satisfy the recommendations for safe interactions among Sponsor and CRO, but it saves the Sponsor significant time and money. Consider the expense of an on-site visit – travel time, transport, rentals/taxis, lodging, meals, entertainment. Occasionally, Sponsors will incur the added cost of consultants hired to achieve sufficient oversight. Moreover, travel availability may influence schedules and force audits to be conducted in a rush or within a limited time frame. All of these factors combine to make the reality of in-person QA audit activities an investment worthy of careful consideration.

The pandemic has given Charles River's Quality Systems teams a reason to emphasize and expand upon the innovative solutions we currently have in place for connecting with Sponsors. Our virtual tours, audits, and communications are secure, flexible, and designed to achieve a transparent collaborative experience that rivals in-person visits. Whether a Sponsor needs to complete routine QA facility qualification or data audits, or oversee their project from a scientific perspective, a virtual experience can help them achieve their goals from the comfort of their desktop. We understand that for many, remote auditing may be the "new" normal, and so have established additional supports to make the experience as simple as possible.

Preparation

Virtual appointments are scheduled in the same manner as in-person events; by filling out a [contact form](#), the Sponsor connects with a Charles River audit host who will make appropriate arrangements for the desired tasks.

Together with their host, the Sponsor will establish detailed agenda to ensure that audit objectives are met. The agenda will identify strategic components such as a daily launch meeting with the Charles River host and subject matter experts, staff interview slots, daily adjournment meetings as required, and a wrap-up meeting at the conclusion of the audit. Prior to the audit, the audit host will send technical specifications and instructions for connecting to the systems that will facilitate the audit (e.g., portal, Microsoft Teams, etc.) along with any necessary access credentials. Sponsors will also receive meeting invitations for prearranged meetings.

EVERY STEP OF THE WAY

Conduct

Remote audits are designed to be flexible and efficient, tailored to a Sponsor's requirements; as such, there are many paths to an effective, successful audit. As with on-site audits, all relevant documents are included as part of a standard audit package. Audit activities are conducted via the agreed-upon platform (e.g., Microsoft Teams, the Charles River portal, etc.). The nature of these tools makes it easy for Sponsors to access and review documents independently and at their leisure, though built-in features like video calls, chat, and email allow the Sponsor to communicate as necessary with the audit host. Documents that are normally available for off-site review are similarly available for download. Regulated data is shared over a secure connection; using supplied credentials, Sponsors can log in to explore the provided records as often as they wish within the audit window.

As with an on-site visit, the virtual audit may include prescheduled or ad hoc discussions of processes, SOPs, and departments. Should a Sponsor have a specific request, the audit host will gather and share materials through the Teams or Portal site. "Sensitive" documents – equipment records housed in an electronic system or redacted versions of curriculum vitae for employees, business continuity plans, or trade-secret/proprietary SOPs, etc. require special controls. In these cases, the audit host will coordinate sharing of sensitive information through a secure Charles River-hosted meeting. This option is also used to demonstrate computerized data collection systems to facilitate understanding and offer Sponsors the chance to ask questions.

The Virtual Tour

As the typical audit agenda includes a facility tour, we have added an optional virtual walkthrough component to our remote audit. This is an excellent opportunity to observe areas of interest in real-time. We conduct virtual tours over a secure platform using a tablet that projects video of the areas within the facility. Whether it's their first visit or fifth, the tour is an interactive experience in which Sponsors can witness lab operations, see enhancements that may

have occurred since their previous audit, understand the differences between different areas within the lab, and ask questions of their tour guide. Best of all, this is all accomplished from the comfort of their desk, with no walking or PPE required.

Close-Out

As with in-person audits, the virtual experience concludes with a final meeting with Test Facility and QA management personnel. This forum is another opportunity for Sponsors to connect with the Charles River team, discuss observations, suggest improvements, and share positive feedback. All observations pertaining to our operations and the remote audit experience itself are considered opportunities to improve or enhance our systems, service, and overall regulatory compliance. We encourage and appreciate our clients' thorough review and feedback and have policies in place to share these with our teams.

Summary

Even in challenging times, Charles River continues to implement solutions that meet our clients' needs. In fact, we've offered remote collaboration tools before they were a necessity. Our proven ability to host remote audits lends confidence in our systems and processes, so clients can expect exceptional science and data integrity. Our experienced quality assurance team will help plan the audit, familiarize Sponsors with the remote audit process and technology, facilitate document reviews, and assist with scheduling interviews. Much of the virtual audit mirrors the onsite experience, featuring pre-audit meetings, a defined scope, a detailed agenda, requested documents and interviews, with the added advantages of greater flexibility, no associated travel or consultant costs, and the ability to perform this critical task from the safety and comfort of the Sponsor desktop.

To get started with a remote audit and/or virtual tour, simply fill out the [request form](#).