



Supporting our Customer's Regulatory Compliance Obligations

Our Client Commitment to Ensuring Quality and Compliance

As the COVID-19 situation continues to evolve, we realize that fulfilling regulatory and quality assurance obligations may present a challenge to our clients with audits and qualification of outsourced vendor/supplier quality system practices. The Charles River Regulatory Compliance and Quality Assurance teams are committed to ensure that our internal quality systems are operating in full compliance with national monitoring authority regulations during these extraordinary times. We also realize that our sponsor and customers may have internal program standards and procedures that require they uphold regulatory audits of these services to validate that they are operating in full compliance.

To respond to these needs we have taken measures to ensure our facilities are monitoring events and any impact on employee safety and business operations. In addition, we are asking our clients to limit visits to our sites for highly business-critical objectives and that visitors will be restricted to our administrative office areas, (e.g. no visitors will be allowed in our laboratories and or vivarium except for a critical study event).

With these restrictions in place, we want to provide an alternative measure to fulfill Client QA audit and qualification of our test sites so that we have continuity of compliance programs.

Each of the Charles River Business Units can provide a Remote Audit Scheme to our customer and client base to ensure that audit objectives are met. We want to provide you with the confidence and assurance that we remain committed to be your "Partner in Compliance".

The following provides an overview of how this program works:

Initiating the Audit

To set up a remote audit of one of our facilities, the request should be communicated through normal channels as

with any other audit request. Please reach out through your normal means of scheduling an audit (either through your QA Contact, your account Representative, Website link, and/or customer service support) who will ensure you are working with the appropriate Quality Assurance representative.

Preparing for the Audit

Audit preparation should be conducted in the same approach as for an onsite audit.

As part of the preparation process please define the scope of the audit and identify key functional personnel that you would like to interview and identify the documentation and records that should be available for review.

Defining the scope of the audit as clearly and early as possible will ensure the audit objectives will meet your expectations. This allows us to properly prepare for the audit, including scanning any paper records for presentation during the online session.

Our Quality Assurance representative will walk you through the remote audit process, which will include:

- i. For client specific documentation (i.e., study related material), the documentation can be uploaded to either

your or our portal for review. These documents could be reviewed prior to the secure online webinar to enhance your audit experience by allowing you to review the documents on your own schedule. Questions could then be asked via email or during the online session.

ii. For non-study related documentation or other documentation not specific to the client (e.g., facility records, training records, SOPs) that are subject to review we offer the ability to access and review these documents during an online webinar. We will provide a means for you to securely and independently review documentation at your leisure during the webinar session without the uncomfortable feeling of possibly having access to out of audit scope material. We can organize documentation to facilitate your reviews, including separate folders for different types of records (e.g., computer validation, SOPs, training).

iii. Interviews can be scheduled during the session as well, allowing interactive discussions via video enabled webinar.

Conducting the Audit

A remote audit need not be conducted in one continuous session. To accommodate your schedule, separate sessions on different days may be conducted. The structure of the audit will be the same as an onsite audit, with opening and closing meetings scheduled with appropriate staff and a dedicated host to respond to all

your requests. Please consider the additional time that may be needed to scan paper documents for review online. Some requests may take additional time though we will make every effort to accelerate the process so that all documents can be reviewed during the scheduled webinar session.

Ongoing and Sustained Support

Our staff, like yours, is closely monitoring the current situation and are taking appropriate precautions. Yet we continue to strive to improve our services and meet customer needs. We are confident in our ability to support these remote audits. The ability to host online remote audits supports your due diligence needs and helps minimize all our potential exposure to COVID-19.

Thank you for continuing to partner with Charles River.

Please feel free to contact me or your sales representative with any questions. You can also visit our COVID-19 webpage for more information and regular updates at www.criver.com/coronavirus-disease-covid-19-updates

Sincerely,

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