

Planned activity for on-site audit	Change to planned activity for remote audit
1 Request to audit the laboratory on an agreed date.	Unchanged , the audit host had still reserved the mutually agreed date.
2 Request to receive the following documents by e-mail, one week prior to the audit date: <ul style="list-style-type: none"> • Quality policy • Validation master plan • List of current, approved procedures • Completed supplier qualification questionnaire. 	Unchanged , the documents will be forwarded as originally requested
3 Opening meeting with audit host and audit team, who are physically present in a meeting room.	A voice over presentation either provided by the audit host remotely on the day of the audit or forwarded with the requested documentation one week prior to the audit.
4 Physical tour of the laboratories and sample storage areas.	A virtual laboratory tour either provided by the audit host/testing experts remotely on the day of the audit or forwarded with the requested documentation.
5 On site documentation review of the following quality management system procedures with the audit host and lead auditor, who are physically present in a meeting room: <ul style="list-style-type: none"> • Sample management • Change, deviation and corrective action management • Results (within and out-of-specification) reporting and release certificate management • Training record review • Computerised systems validation reports and operating procedures. 	Remote 'desktop' review of the requested documentation solely by the lead auditor without the other auditor(s), testing experts or the audit host being present. The lead auditor may contact the audit host if necessary.

6	<p>On-site documentation review of the following analytical test methods and qualification reports with an auditor and the technical experts, of whom are all physically present in a meeting room:</p> <ul style="list-style-type: none"> • Potency • Protein • Impurities • Biological identity. 	<p>Remote 'desktop' review of the requested documentation by the auditor(s) without the lead auditor or audit host being present. Testing experts may be contacted if necessary.</p>
7	<p style="text-align: center;">Closing meeting</p>	<p>At the end of the day, the audit team will convene remotely to discuss any potential findings from their individual 'desktop' reviews.</p> <p>Once the audit team's position is aligned, the audit host and testing experts will join a remote closing meeting. If the auditors have any open questions that cannot be answered immediately by the audit host or testing experts, then the lead auditor will send the audit host a list of open queries requiring clarification.</p> <p>Following the clarification of any outstanding queries, the lead auditor will prepare a draft report.</p>
8	<p>Audit report</p>	<p>Unchanged, a draft report with observations and recommendations for improvement (if any) will be submitted to the audit host for review and acceptance within the originally agreed timeframe.</p>
9	<p>Corrective action follow-up</p>	<p>Unchanged</p>