

# VIRTUAL REMOTE AUDITING:

## Part of our [Quality Systems](#) Services



*The generation and execution of a stage appropriate yet comprehensive audit program is critical for regulatory and developmental success. Failure to properly prepare, execute and maintain a suitable audit program is a common source of failure and delay in the Cell and Gene Therapy Industry. DHC combines specialized in-house experience and the use of a proprietary toolkit to deliver your individual audit or audit program remotely, comprehensively, to a predefined schedule—and in alignment with the same regulatory requirements as those of an onsite audit.*

**DHC's formula for success is based on a rigorous, tried-and-tested process of planning, dialogue, execution, reporting, and follow-up:**

- **Planning/Dialogue:** We work with you closely to carefully define the audit requirements that will guide the meticulous preparation of documentation to facilitate a comprehensive review.
- **Execution:** DHC's experienced auditors apply proprietary tools to systematically review facilities and documentation that will inform the content of a secure virtual meeting.
- **Reporting:** An audit report is generated in a defined time frame that details findings by criticality in a structured format, to drive successful remediation.
- **Follow up:** If needed—and once plausible due to social distancing requirements—an on-site audit is performed to verify remediation of any findings identified during the remote audit.

### **Confidentiality is of Paramount Importance**

The security and confidentiality of your electronic or electronically-transmitted information is as critical to us as it is to you. Our rules surrounding confidentiality apply to remote audits just as they do for all of our services, including audits conducted face-to-face. All information collected during both the planning and execution of the virtual remote audit can be deleted once our work is completed. Information classified as certification records by regulatory bodies will be retained with the consent of the client.



Video sharing capabilities allow for a real-time location-specific review.

*The worldwide CoVID-19 pandemic has changed many things about our working environments as we know them. Dark Horse has developed a virtual remote auditing methodology in response to the new need to move cell & gene therapies forward without face-to-face contact. Most of our services are already available in a remote capacity; this particular offering, however, is new as of April of 2020. To review the white paper on this subject, please click [here](#).*

Face-to-face calls are well-suited for dialogue and planning stages.

