



TOGETHER FOR INSPECTION READINESS

The pharmaceutical companies and regulatory authorities are adapting to the new ways of ensuring compliance from a drug safety and efficacy perspective. As a result, there is an increasing trend of conducting virtual audits and inspections in the new normal.

Our team of experienced quality auditors provides expertise in onsite and virtual auditing across Good Pharmacovigilance Practices (GPvP), Good Clinical Practices (GCP) and Good Clinical Laboratory Practices (GCLP). Our Quality Assurance experts can help you with all your Quality audit requirements without compromising or increasing risk of non-compliance in the fields of Pharmacovigilance, Clinical and Bioanalytical systems.

YOUR TRUSTED PARTNER FOR VIRTUAL AUDITING SERVICES

Virtual or e-auditing is an electronic format of auditing technique. It is the next generation mode of business continuity in which the sites can be assessed and facilitated in crisis like pandemic or political unrest irrespective of the location.



- Minimum dependency on auditee
- Anytime availability
- Undisturbed controlled environment



- Customizable audit plan
- Targeted approach as per risk based analysis to match large volumes
- Virtual audit approach selected based on audit risk assessment



- Increased frequency
- Continuous and real time review of data
- Better quality data review



- Adoption of relevant technology and risk management tools to increase efficiency
- Use of digital platforms
- Enhanced ability to visualize the facility, equipment, and processes



- Less dependency on travel or region
- Minimal logistics required
- Eliminate back and forth training or preparedness

VIRTUAL AUDIT PROCESS

Virtual audit planning and selection of communication tools

Scheduling virtual audit

Communication with auditee of audit plan/ agenda and pre-audit document request

Auditee to submit pre-audit documents

Conduct virtual audit

Audit report communication

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Audit report response and CAPA review

Audit closure and relevant communication

APCER CAPABILITIES IN VIRTUAL AUDITING



Team of 15+ Highly experienced auditors with expertise in virtual auditing of domains like GPvP, GCP and GCLP



Robust auditing process and consulting derived from hosting multiple EU and USFDA inspections



Conducted 50+ virtual audits across time zones



End to end support for building virtual audit program



AIR (Anytime Inspection Ready) program for hosting unannounced regulatory inspection(s)



Customized, flexible and scalable operating model



24x7 direct access to EU QPPV as required for QMS queries



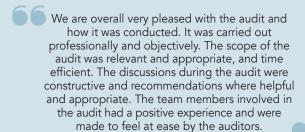
Proven track record in project execution and achieving KPIs



Experience of managing electronic tools e.g. LMS, DMS, CAPA tracking



Real-time reporting that fosters transparency and accountability



QPPV and Head of Pharmacovigilance



Associate Vice President, Clinical Development

much helpful.

Together for better health

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • UK: (+44) 208 326 3220 • Asia: (+91) 11 4650 0802 For Business enquiries, please email at: marketing@apcerls.com For General enquiries, please email at: info@apcerls.com