APCER LIFE SCIENCES
Together for better health

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.

Accessibility

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

Agile Methodology

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

Accelerated Review

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

Use of Technology

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

Cost Effectiveness

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

VIRTUAL AUDIT PROCESS

1. Virtual audit planning and selection of communication tools
2. Scheduling virtual audit
3. Communication with auditee of audit plan/ agenda and pre-audit document request
4. Auditee to submit pre-audit documents
5. Conduct virtual audit
6. Audit report communication
7. Audit report response and CAPA review
8. 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

Conducted 50+ virtual audits across time zones

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

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

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

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

End to end support for building virtual audit program

Customized, flexible and scalable operating model

Proven track record in project execution and achieving KPIs

Real-time reporting that fosters transparency and accountability

> We are overall very pleased with the audit and how it was conducted. It was carried out professionally and objectively. The scope of the audit was relevant and appropriate, and time efficient. The discussions during the audit were constructive and recommendations where helpful and appropriate. The team members involved in the audit had a positive experience and were made to feel at ease by the auditors.
>
> QPPV and Head of Pharmacovigilance

> We are thankful to APCER QA team for leading the preparedness of USFDA Inspection. Your support has made us confident to host inspections. Gap analysis activity conducted before inspection was much helpful.
>
> Associate Vice President, Clinical Development

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