APCER LIFE SCIENCES
Together for better health

BROCHURE

Together for Inspection Readiness

Quality Assurance Services

The pharmaceutical companies and regulatory authorities are adapting to the new ways of ensuring compliance in terms of safety and efficacy of drugs. Regulatory authorities have shifted to conducting inspections virtually. Therefore, conducting virtual audits has become an increasing trend and a new normal.

APCER's 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 the quality audit requirements without any risk of non-compliance in Pharmacovigilance, Clinical, and Bioanalytical systems. Trained and qualified auditors with relevant GxP experience are also IRCA certified Lead Auditors for the Quality Management System.

Your Trusted Partner for Virtual Auditing Services

Virtual or e-auditing is an electronic format of the auditing technique. It is the next-generation mode of business continuity where sites, regardless of location, can be evaluated and supported even during crises like pandemics and political upheavals.

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

Efficiency through Technology

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

Cost Effectiveness

- Less dependency on travel or region
- Minimal logistics required
- Elimination of 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. Pre-audit documents review and submission
5. Conduct virtual audit (live demo and interviews)
6. Audit report release
7. Audit report response and CAPA plan review
8. Audit closure and relevant communication

APCER Key Features

Expertise: Team of 20+ highly experienced auditors with expertise in virtual auditing of domains like GPvP, GCP, and GCLP

Experience: Conducted 200+ virtual audits across time zones

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

Availability: 24x7 direct access to QPPV as required for QMS queries

Tools and Systems: Experience of managing electronic tools, e.g., LMS, DMS, CAPA tracking

Robust auditing process and consulting derived from hosting multiple inspections for EMA, MHRA, and USFDA

End-to-end support for building virtual audit program

Customizable, flexible, and scalable operating model

Proven track record in project execution and achieving KPIs

Real-time reporting that fosters transparency and accountability

Testimonials

> **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 were 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 for 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

APCER LIFE SCIENCES
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Part of APC Group

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.

We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company.

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (+91) 11 4650 0802

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