



BROCHURE

Together for Inspection Readiness

Quality Assurance Services

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



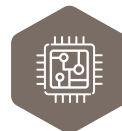
Agile Methodology

- 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

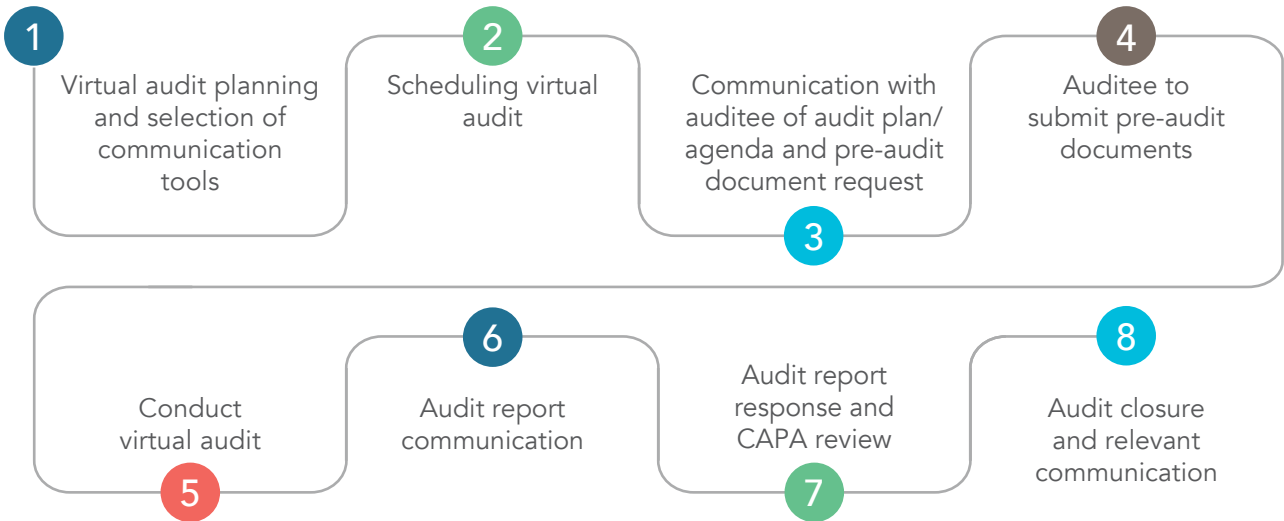
- Adoption of relevant technology and risk management tools to increase efficiency
- Use of digital platforms
- Enhanced ability to visualize the facility, equipment, and processes



Cost Effectiveness

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

Virtual Audit Process



The APCER Advantage



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

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 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
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 27001:2013, 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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